EXHIBIT B

1929076

Cause No._____

County of Walker Plaintiff,	§	In the District Court
v.	§	of Walker County, Texas
	§	Walker County - 12th District Court
Abbott Laboratories; Abbott Laboratories, Inc.; Abbvie Inc.; Actavis LLC; Actavis, Inc. f/k/a Watson; Actavis Elizabeth LLC; Actavis Pharma, Inc.; Advanced Pharma, Inc., d/b/a/ Avella of Houston; Allergan Finance LLC f/k/a Actavis, Inc. a/k/a Watson Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLC; Alpharma Pharmaceuticals Inc; Alpharma Pharmacecuticals LLC; AmerisourceBergen Drug Corporation; Apotex Inc., Aveva Drug Delivery Systems, Inc.; Apotex Inc.; Cardinal Health, Inc.; Caremark Rx, L.L.C.; CaremarkPCS Health, LLC; Caremark LLC; Caremark PCS LLC; Cephalon, Inc.; CuraScript SV Specialty Distribution, LLC; CuraScript, Inc; CVS Caremark Corporation; CVS Health Corporation; CVS Pharmacy, Inc.; Depomed, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Express Scripts Holding Company; Express Scripts, Inc.; Fresenius USA Manufacturing, Inc.; Fresenius Kabi USA; HD Smith Drug Co.; ICU Medical Sales Inc.; ICU Medical Inc.; Impax Laboratories, Inc.; Insys Therapeutics, Inc.; Insys Manufacturing, LLC; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceuticals, Inc.; JM Smith Corporation; Johnson & Johnson;	§	_____ Judicial District

Knoll Pharmaceutical Company;	§
Mallinckrodt PLC; Mallinckrodt	§
LLC; Mallinckrodt Pharmaceuticals;	§
Mallinckrodt Inc.; Mckesson	§
Corporation; McKesson	§
Medical-Surgical, Inc.; Medco	§
Health Solutions of Texas, LLC;	§
Mission Pharmacal Company;	§
Mylan, Inc.; Mylan Specialty, LP;	§
Mylan Pharms Inc.; Mylan	§
Pharmaceuticals, Inc.; Mylan	§
Technologies Inc.; Navitus	§
Management, LLC; Navitus	§
Holdings, LLC; Navitus Health	§
Solutions, LLC; Neos Therapeutics	§
Inc.; Nesher Pharmaceuticals USA	§
LLC; NexGen Pharma, Inc.; Noven	§
Pharmaceuticals, Inc.; OptumRx,	§
Inc.; OptumRX Administrative	§
Services, LLC; Optum, Inc.;	§
Ortho-Mcneil-Janssen	§
Pharmaceuticals, Inc. n/k/a Janssen	§
Pharmaceuticals, Inc.;	§
Paddock Laboratories, LLC;	§
Par Pharmaceuticals, Inc.;	§
Perrigo Company; Prime	§
Therapeutics LLC; Purdue	§
Pharma, Inc.; Purdue Pharma, L.P.;	§
Purdue Pharmaceuticals, L.P.;	§
QS/1Data Systems of JM Smith	§
Corporation; Teva Pharmaceutical	§
Industries, Ltd.; Teva	§
Pharmaceuticals USA, Inc.; The	§
Purdue Frederick Company;	§
UnitedHealthcare of Texas, Inc.;	§
UnitedHealth Group Incorporated;	§
Watson Laboratories, Inc.; Zogenix,	§
Inc.; and Zydus Pharmaceuticals	§
USA Inc.,	§
Defendants.	§

Contents

Plaintiff's Original Petition and Jury Trial Demand

Plaintiff, the County of Walker, Texas, ("Walker County" or "County"), by and through the undersigned attorneys and against Defendants, alleges as follows:

Introduction

The Staggering Impact of the Opioid Epidemic

1. The United States is in the midst of an opioid epidemic caused by Defendants' fraudulent marketing, distribution, and sales of prescription opioids ("opioids"). This epidemic has resulted in: rampant addiction rates and the tragic loss of hundreds of thousands of lives; soaring costs for medical care, including huge burdens on the Medicare system; increased criminal activity leading to an exponential increase in the costs of policing; increasing rates of incarceration; and an increase in unemployment resulting in tax revenue losses.

2. The rampant distribution and use of opioids is killing tens of thousands of Americans every year. According to the US Department of Health and Human Services, drug overdose is now the leading cause of death among people under 50 years of age. Per the Centers for Disease Control and Prevention (the "CDC"), more than 90 Americans die each day from opioid overdose. Indeed, for the year 2016 alone, Americans suffered more than 600,000 drug overdoses and more than 63,000 drug-related deaths, with more than 66 percent of them—42,249 deaths—involving opioids. This 2016 opioid-related death rate represents a 27.9% increase over 2015. Furthermore, deaths from the opioid drug fentanyl doubled for that same period.

3. In addition to killing many thousands of people, Defendants' marketing, distribution, and sales of opioids is causing additional public health crises. For example,

hepatitis C virus ("HCV") rates have increased almost 300 percent (including in infants exposed to hepatitis C), and there have been similar increases in the hepatitis B virus ("HBV"), HIV, endocarditis, septic arthritis, epidural abscess, and osteomyelitis. Additionally, more than two newborns per hour in the U.S. are diagnosed with opioid withdrawal, known as neonatal abstinence syndrome (NAS).

4. The financial impact of the opioid crisis has been no less staggering: from 2001 to 2017, the cost of the opioid crisis in the United States exceeded $1 trillion, and it is estimated to cost an additional $500 billion by 2020.

5. President Donald Trump, on October 26, 2017, declared the opioid crisis a "nationwide public health emergency."

6. Unlike many other public health epidemics, the opioid crisis was entirely avoidable. The opioid crisis is not like influenza, HIV-AIDS, or a natural disaster like a hurricane or earthquake. Instead, the opioid epidemic is a public health crisis caused by corporate greed: the makers, distributors, and sellers of opioids caused America to become awash in these highly-addictive pills so that these corporations could make billions of dollars in profits.

The Cause of the Opioid Epidemic

7. Beginning in the late 20th century and continuing to the present, Defendants flooded the market with prescription opioids, causing massive harm to public health. As described in more detail below, Defendants accomplished this expansion in three primary ways. First, pharmaceutical manufacturers ("Manufacturing Defendants," as defined below) misled the public (including prescribing physicians) into believing that opioids were safer, more effective, and less likely to form an addiction than they really were. Second, the pharmacy benefit managers ("PBM Defendants," as defined below) accepted

payments from the Manufacturing Defendants and ensured that opioids were widely available, regularly prescribed, and quickly reimbursed. Third, the Manufacturing Defendants, pharmaceutical distributors ("Distributor Defendants," as defined below), and pharmacies ("Pharmacy Defendants," as defined below) each failed to take action in response to clear evidence that opioids were being distributed and used in an unlawful manner.

8. What makes Defendants' efforts particularly nefarious—and dangerous—is that, unlike other prescription drugs marketed unlawfully in the past, opioids are highly addictive controlled substances. In other words, Defendants deceptively and unfairly targeted a vulnerable patient base that—physically and psychologically—could not turn away from their drugs.

9. Defendants' marketing efforts were both ubiquitous and persuasive. Their deceptive messages tainted virtually every source of information that doctors could rely on to make informed treatment decisions. Defendants targeted not only pain specialists, but also primary care physicians, nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess Defendants' misleading statements. Among other things, Defendants literally wrote the book on how to prescribe opioids by controlling the treatment guidelines for these drugs. Defendants callously manipulated what doctors wanted to believe—namely, that opioids represented a compassionate means of relieving their patients' real suffering. And to further enhance this emotional plea, Defendants marketed similar deceptive messages directly to patients so that they would go to physicians demanding these "miracle" drugs.

10. This nefarious conduct resulted in a sharp increase in the number of prescriptions for opioids. More than 250 million opioid prescriptions were issued in 2012 alone, almost enough prescriptions for every adult in the United States to be prescribed a bottle of pills. From 1999 to 2008, sales of prescription opioids increased by 400 percent nationally. During that same time, overdose deaths caused by prescription opioids and hospital admissions for opioid abuse also increased 400 percent. Even heroin abuse during this same time period was largely driven by prescription opioid sales, with 4 out of 5 heroin users reporting that their heroin addiction began with the abuse of prescription painkillers.

11. Children have not escaped the scourge of prescription opioid and heroin addiction. By 2015, 122,000 people under the age of 18 were addicted to prescription opioids, with an additional 21,000 driven to heroin use.

The Impact of the Opioid Epidemic on Walker County

12. Walker County has suffered considerable damages from the opioid epidemic in the past and will continue to suffer damages in the future. Data from the CDC shows that for the year 2015, Walker County residents received far more opioids per person (601 morphine mg equivalents "MME") than the Texas statewide average (420.63 MME). Furthermore, Walker County also had higher than the Texas and national averages for the number of opioid pills prescribed per month per Medicare Part D enrollee. Each Medicare Part D enrollee in Walker County was prescribed 2.09 months-worth of opioids for every 30-day period (in short, two times the number of pills that would have been reasonable for even a legitimate patient). The same CDC data showed that for the year 2016, the number of opioid drug deaths per 100,000 persons in Walker County's Congressional District 8 was 0.7% higher than an already grossly inflated state average. Indeed, there were 583

opioid drug-related deaths in District 8 in 2016, representing more than one-fifth of the total number of opioid drug-related deaths for all of Texas.

13. The CDC reports that the Walker County opioid mortality rate more than quadrupled from 2000 to 2016. These drug-related deaths grew steadily from 2–3.9 per 1,000 people in 1999 to 8–9.9 per 1,000 people in 2016.

14. Every Walker County purchaser of private health insurance paid higher premiums, co-payments, and deductibles because of Defendants' actions. Insurance companies pass onto their insureds the expected cost of future care—including opioid-related coverage. Accordingly, insurance companies factored in the unwarranted and exorbitant healthcare costs of opioid-related coverage caused by Defendants and charged that back to insureds in the form of higher premiums, deductibles, and co-payments.

Rule 47 Statement of Monetary Relief Sought

15. Pursuant to Texas Rule of Civil Procedure No. 47, Plaintiff states that it seeks monetary relief over $1,000,000.

Venue and Jurisdiction

16. This Court has personal jurisdiction over these Defendants because they carry on a continuous and systematic part of their business within Texas, have transacted substantial business with Texas entities and residents, and have caused harm in Texas as a result. Each of the non-resident Defendants has done business in the state, has purposefully availed itself of the privileges of conducting business within Texas, and/or has sufficient minimum contacts with the State of Texas generally and Walker County specifically to render it subject to the Court's jurisdiction.

17. Plaintiff specifically alleges that the claims and causes of action set forth in this petition are entirely based on the provisions of Texas law. Plaintiff specifically disclaims any cause of action based on federal law and does not seek any relief on the basis of federal law or any violation thereof. There is no claim of fraud on the federal Food and Drug Administration. One or more of the Defendants named herein is a resident of the State of Texas, so there is not complete diversity among the parties.

Discovery Control Plan

18. Plaintiff, Walker County, designates this case as a Level 3 case requiring a discovery control plan tailored to the circumstances of this specific suit.

Parties

a. Plaintiff

19. This action is brought for and on behalf of Walker County, Texas, which provides a wide range of services on behalf of its residents, including services for families and children, public health, emergency care, public assistance, law enforcement, and social services, as well as medical and prescription benefits that the County provides to its employees and retirees.

b. Defendants

20. Each of the parties named below manufactures, promotes, sells, and/or distributes opioids in Texas and in Walker County.

Manufacturing Defendants

21. The Defendants identified in paragraphs 22 to 48 shall be referred to herein as "Manufacturing Defendants."

22. Abbott Laboratories is a corporation organized under the laws of Illinois with its principle place of business in Abbott Park, Illinois. Abbott Laboratories, Inc. is an Illinois corporation with its principal place of business in Abbott Park, Illinois (collectively "Abbott"). Both Abbott Laboratories and Abbott Laboratories, Inc. may be served through their registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

23. Abbvie Inc. ("Abbvie") is a Delaware corporation with its principal place of business in North Chicago, Illinois, and may be served through its registered agent for service of process, CT Corporation System, 208 S. LaSalle Street, Suite 814, Chicago, IL 60604. Knoll Pharmaceutical Company ("Knoll") has been a wholly-owned subsidiary of Abbvie from January 1, 2013. Knoll Pharmaceutical Company is a New Jersey corporation with its principal place of business in Parsippany, New Jersey, and may be served through its registered agent for service of process, CT Corporation System, 208 S. LaSalle Street, Suite 814, Chicago, IL 60604.

24. Knoll irresponsibly marketed narcotics, such as Vicodin, through whimsical toys and souvenirs and did so to boost the sales of opioids. Taking advantage of the fact that Vicodin was not regulated as a Schedule II controlled substance for many years, and the fact that physicians and consumers did not fully appreciate the highly addictive nature of Vicodin, Knoll advertised Vicodin with tag lines such as "The Highest Potency Pain Relief You Can Still Phone In." This tag line came as part and parcel of souvenirs like a "Vicodin" fanny pack and water bottle, both bearing the name of Vicodin, the opioid Knoll

was promoting. This irresponsible marketing of a narcotic drug caused doctors and patients to believe Vicodin was safer than it really was, to the detriment of people in Walker County.

25. Abbvie began manufacturing, developing, promoting, marketing, and selling the opioid drug, Vicodin, in the U.S. and in Walker County beginning January 1, 2013. On information and belief, it continues to do so at the time of filing this pleading.

26. Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in January 2013. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Allergan Finance, LLC as of October 2013. Allergan Finance, LLC is a Nevada Corporation with its principal place of business in Parsippany, New Jersey, and may be served through its registered agent for service of process, The Corporation Trust Company of Nevada, 701 S. Carson St., Suite 200, Carson City, NV 89701. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.), and may be served through its registered agent for service of process, Corporate Creations Network, Inc., 8275 South Eastern Ave., #200, Las Vegas, NV 89123. Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc., and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, TX 75201. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey, and may be served through its registered agent for service of process,

Corporate Creations Network, Inc., 3411 Silverside Rd., Tatnall Building, Suite 104, Wilmington, DE 19810. On information and belief, Actavis Elizabeth LLC is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202. Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Each of these Defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Allergan Finance, LLC, Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis"). Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009. Actavis manufactures, promotes, sells, and distributes opioids in nationally, including in Texas and Walker County.

27. Alpharma Pharmaceuticals Inc. is a Delaware corporation with its principal place of business located in New Jersey. Alpharma operates as a subsidiary of Defendant King Pharmaceuticals, Inc, which is itself a wholly owned subsidiary of Defendant Pfizer, Inc. On information and belief, Alpharma Pharmaceuticals LLC is a Tennessee corporation, with its principal place of business located in New York (collectively "Alpharma").

28. Cephalon, Inc. ("Cephalon") is a corporation organized under the laws of Delaware and has its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. As

of October 2011, Cephalon, Inc. operates as a subsidiary of Defendant Teva Pharmaceuticals Industries, Ltd.

29. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania, and may be served through its registered agent for service of process, The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. Endo Health Solutions Inc. is a wholly-owned subsidiary of Endo Pharmaceuticals, Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania, and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, TX 75201. (Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc. are referred to as "Endo").

30. Endo develops, markets, and sells opioid drugs nationally, including in Texas and Walker County. Endo also manufactures and sells generic opioids nationally, including in Texas and Walker County, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

31. Fresenius USA Manufacturing, Inc. is a corporation organized under the laws of Delaware and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. Fresenius Kabi USA is a related entity associated with Fresenius USA Manufacturing Inc. through which Fresenius USA Manufacturing Inc. is operating and conducting business in this State (collectively, "Fresenius").

32. Insys Therapeutics, Inc. is a corporation organized under the laws of Delaware and may be served through its registered agent for service of process, CT Corporation System,

1999 Bryan Street, Suite 900, Dallas, Texas 75201. Insys manufactures, promotes, sells, and/or distributes opioids nationally and in Walker County, including the opioid drug Subsys (fentanyl sublingual spray). Insys Manufacturing LLC, a Texas resident, is a related entity associated with Insys Therapeutics, Inc. through which Insys Therapeutics Inc. is operating and conducting business in this state, with its principle place of business at 2700 Oakmont Drive, Round Rock, Texas 78665 (collectively, "Insys").

33. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, TX 75201. Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey, and may be served through its registered agent for service of process, Attention: Legal Department, One Johnson & Johnson Plaza, New Brunswick, NJ 08933. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutical Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen").

34. Janssen manufactures, promotes, sells, and distributes opioids nationally, including in Texas and Walker County.

35. King Pharmaceuticals, LLC ("King") is a wholly owned subsidiary of Pfizer, Inc., which acquired the Tennessee drug maker in October 2010. The corporation is organized and existing under the laws of the state of Delaware and has a principal place of business at 235 E. 42nd Street, New York, New York 10017. King may be served through its registered agent for service of process, CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919. Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, NY 10017. Pfizer may be served through its registered agent for service of process, The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

36. Mylan, Inc. is organized as a corporation under the laws of Pennsylvania with a principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Mylan conducts its pharmaceutical business operations through various entities, including Mylan Specialty, LP, Mylan Pharms Inc., and in Texas through Mylan Pharmaceuticals, Inc., which may be served through its registered agent Corporation Service Company, 211 East 7th Street, Suite 620, Austin, Texas 78701. Mylan Technologies Inc. is a West Virginia corporation, having its principal place of business at 110 Lake Street, Saint Albans, Vermont 05478 (collectively, "Mylan").

37. Nesher Pharmaceuticals USA LLC, a generic pharmaceutical manufacturer located in St. Louis, MO, is a subsidiary of privately held Zydus Pharmaceuticals USA Inc. Zydus Pharmaceuticals USA Inc. is a corporation organized and existing under the laws of New

Jersey, with its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

38. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware and may be served through its registered agent for service of process, The Prentice-Hall Corporation System, Inc., 251 Little Falls Drive, Wilmington, DE 19808. Purdue Pharma L.P. is, through its ownership structure, a Texas resident. Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and may be served through its registered agent for service of process, Corporation Service Company, 80 State Street, Albany, NY 12207. The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut, and may be served through its registered agent for service of process, The Prentice-Hall Corporation System, Inc., 251 Little Falls Drive, Wilmington, DE 19808 (collectively, "Purdue").

39. Teva Pharmaceuticals Industries, Ltd., is an Israeli company with its principal place of business in Petah Tikva, Israel, and US headquarters at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva Pharmaceuticals USA, Inc., an American subsidiary of Teva Pharmaceuticals, Ltd., is a corporation organized under the laws of Delaware, with headquarters at 19 Hughes, Irvine, California 92618 (collectively, "Teva").

40. ICU Medical Sales Inc. is a drug manufacturer and corporation organized under the laws of Delaware with its principal place of business in San Clemente, California, and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. ICU Medical Inc. is a related entity associated with ICU Medical Sales Inc. through which ICU Medical Sales Inc. is operating

and conducting business in this State (collectively, "ICU"). ICU is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including Meperidine hydrochloride (ANDA # 088432) and morphine sulfate (NDA # 019916 and NDA # 019917).

41. Impax Laboratories, Inc. is a drug manufacturer and a corporation organized under the laws of the State of Delaware with its principal place of business located at 30831 Huntwood Avenue, Hayward, California 94544. Impax is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including oxymorphone hydrochloride (ANDA # 079087).

42. Mission Pharmacal Company ("Mission") is a drug manufacturer and organized as a corporation under the laws of Texas with a principal place of business at 10999 IH-10 West, Suite 1000, City View Building, San Antonio, Texas 78230. Mission may be served through its registered agent for service of process, Neill B. Walsdorf, 10999 IH-10 West, Suite 1000, City View Building, San Antonio, Texas 78230. Mission is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including hycofenix (guaifenesin, hydrocodone bitartrate, pseudoephedrine hydrochloride) (NDA # 022279.

43. Neos Therapeutics, Inc. is a drug manufacturer and a limited partnership organized under the laws of Texas with its principle place of business at 2940 North Highway 360, Suite 400, Grand Prairie, Texas 75050. Neos conducts its pharmaceutical business through various entities, including Neos Therapeutics Brands LLC, Neos Therapeutics, LP, and may be served through its registered agent for service of process, CT Corporation System,

1999 Bryan Street, Suite 900, Dallas, Texas 75201. Neos is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including hydrocodone polistirex and chlorpheniramne (ANDA # 091671).

44. NexGen Pharma, Inc. ("NexGen") is a drug manufacturer and corporation organized under the laws of Texas with its principal place of business at 1000 Cole Avenue, Rosenberg, Texas 77471. NexGen may be served through its registered agent for service of process, Business Filings Incorporated, 701 Brazos Street, Suite 720, Austin, Texas 78701. NexGen is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including butalbital, acetaminophen, caffeine, and codeine phosphate (ANDA # 076560).

45. Noven Pharmaceuticals, Inc. is a drug manufacturer and a Delaware corporation with a principal place of business at 11960 S.W. 144th Street, Miami, Florida 33186. Noven is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including fentanyl transdermal system (ANDA # 077775).

46. Paddock Laboratories, LLC ("Paddock") is a drug manufacturer and a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 3940 Quebec Avenue N, Minneapolis, MN 55427. Upon information and belief, Paddock is a wholly owned subsidiary of Defendant Perrigo Company ("Perrigo"). Upon information and belief, Defendant Perrigo Company is a corporation organized and existing under the laws of Michigan, having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Paddock is identified by the FDA as the

sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including hydromorphone hydrochloride extended-release (ANDA # 204278).

47. Par Pharmaceuticals, Inc. ("Par") is a drug manufacturer and a New York corporation with its principal place of business in Chestnut Ridge, New York. Par is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including morphine sulfate extended release (ANDA # 200812), oxymorphone hydrochloride (ANDA # 200792), and fentanyl transdermal system (ANDA # 077062).

48. Zogenix, Inc. is a drug manufacturer and a Delaware corporation with its principal place of business at 12400 High Bluff Drive, Suite 650, San Diego, California, 92130. Zogenix is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including Zohydro ER (NDA # 202880).

Pharmacy Defendants

49. The Defendants identified in paragraph 49 shall be referred to herein as "Pharmacy Defendants."

50. Advanced Pharma, Inc. is a corporation organized under the laws of Texas and has its principal place of business at 9265 Kirby Dr., Houston, Texas 77054. Advanced Pharma, Inc. was purchased by Avella Specialty Pharmacy in 2016, and does business as Avella Specialty Pharmacy or Avella of Houston. Advanced Pharma, Inc., Avella Specialty Pharmacy, and Avella of Houston are referred to here as "Advanced Pharma".

Distributor Defendants

51. The Defendants identified in paragraphs 52 to 63 shall be referred to herein as "Distributor Defendants."

52. AmerisourceBergen Drug Corporation ("Amerisource") is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania, and may be served through its registered agent for service of process, The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. Amerisource does substantial business in Texas and, upon information and belief, Amerisource is a pharmaceutical distributor licensed to do business in Texas. Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers to customers nationally, including in Texas and Walker County.

53. Defendant Aveva Drug Delivery Systems, Inc. ("Aveva") is a corporation organized and existing under the laws of the State of Florida, with its principal place of business at 3250 Commerce Parkway, Miramar, Florida 33025. Aveva was purchased by Defendant drug manufacturer Apotex Inc. in 2012. Apotex Inc. ("Apotex") is a corporation organized and existing under the laws of Canada, with its principal place of business in Ontario, Canada. Apotex manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

54. Cardinal Health, Inc. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio, and may be served through its registered agent for service of process, CT Corporation System, 4400 Easton Commons, Suite 125, Columbus, OH 43219. Cardinal does substantial business in Texas and, upon information and belief, Cardinal is a pharmaceutical distributor licensed to do business in Texas. Cardinal

distributes pharmaceuticals to retail pharmacies and institutional providers to customers nationally, including in Texas and Walker County.

55. CuraScript, Inc. ("CuraScript") is a pharmaceutical distributor with its principal place of business in Dover, Delaware and may be served through it's the Secretary of State for service of process, One Express Way, St. Louis, Missouri 63121. CuraScript SV Specialty Distribution LLC is a pharmaceutical distributor with its principal place of business in Dallas, Texas and may be served through its registered agent, Diahvion Burks for service of process at 9737 Forest Lane, Apt. 227, Dallas, Texas 75243.

56. CuraScript does substantial business in Texas and, upon information and belief, CuraScript is a pharmaceutical distributor licensed to do business in Texas. CuraScript distributes pharmaceuticals to retail pharmacies and institutional providers to customers nationally, including in Texas and Walker County.

57. HD Smith Drug Co. ("HD Smith") is a corporation organized under the laws of Delaware with its principal place of business located at 3063 Fiat Avenue, Springfield, Illinois 62703. HD Smith does substantial business in Texas and, upon information and belief, HD Smith is a pharmaceutical distributor licensed to do business in Texas. HD Smith distributes pharmaceuticals to retail pharmacies and institutional providers to customers nationally, including in Texas and Walker County. In November 2017, Defendant AmerisourceBergen announced its intention to acquire HD Smith.

58. JM Smith Corporation d/b/a QS/1Data Systems of JM Smith Corporation ("JM Smith"). JM Smith is a South Carolina corporation with its principal place of business in Spartanburg, South Carolina, and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. JM

Smith does substantial business in Texas and, upon information and belief, JM Smith is a pharmaceutical distributor licensed to do business in Texas. JM Smith distributes pharmaceuticals to retail pharmacies and institutional providers to customers nationally, including in Texas and Walker County.

59. Mallinckrodt PLC ("Mallinckrodt") is an Irish public limited company with its corporate headquarters in Staines-Upon-Thames, Surrey, United Kingdom and maintains a U.S. headquarters at 675 McDonnell Boulevard, St. Louis, Missouri 63042. Mallinckrodt distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Walker County. Mallinckrodt sells powerful, addictive opioids in Texas, such as oxycodone and hydrocodone and other opioids through third party drug distributors, such as Defendants Advanced Pharma, Inc. and Avella of Houston.

60. Mallinckrodt LLC, is a wholly owned subsidiary of Mallinckrodt PLC and is a Delaware limited liability company with its principal place of business in St. Louis, Missouri. Mallinckrodt LLC is registered to do business in Texas and has been since 1989. Mallinckrodt LLC may be served in Texas through its registered agent: The CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

61. Mallinckrodt Pharmaceuticals ("Mallinckrodt Pharma") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Hazelwood, Missouri.

62. Mallinckrodt Inc. is a Delaware corporation having its principal place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042. Mallinckrodt PLC, Mallinckrodt LLC, Mallinckrodt Pharmaceuticals, and Mallinckrodt Inc. are collectively referred to as "Mallinckrodt".

63. McKesson Corporation is a Delaware corporation with its principal place of business in San Francisco, California, and may be served through its registered agent for service of process, CSC - Lawyers Incorporating Service, 211 E. 7th Street, Suite 620, Austin, TX 78701. Upon information and belief, McKesson is a pharmaceutical distributor licensed to do business in Texas. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including in Texas and Walker County. McKesson Corporation also does business in Texas under the entity names McKesson Corporation at 3301 Pollock Drive, Conroe, Texas 77303, and McKesson Medical-Surgical Inc. at 20710 Hempstead Road, Houston, Texas 77065 (collectively, "McKesson").

PBM Defendants

64. The Defendants identified in paragraphs 65 to 93 shall be referred to herein as "PBM Defendants."

65. CVS Health Corporation ("CVS Health"), formerly known as CVS Caremark Corporation ("CVS Caremark") is the sole shareholder of CVS Pharmacy, Inc. ("CVS Pharmacy"), which is the sole member of Caremark Rx, L.L.C. ("Caremark Rx"), which is the sole member of Caremark, L.L.C. ("Caremark"). CVS Health is a pharmacy benefit manager ("PBM") with its principal place of business at Woonsocket, Rhode Island, and may be served through its registered agent for service of process, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. Caremark, L.L.C. may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

66. On information and belief, CVS Health is the direct or indirect parent company of CaremarkPCS Health, L.L.C., which is registered to do business in Texas (since at least 2009) and may be served in Texas through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

67. Caremark PCS, L.L.C., is a Delaware limited liability company formerly known as AdvancePCS Inc., which was founded in 1996 and is based in Irving, Texas. Caremark PCS, L.L.C. is registered to do business in Texas and may be served by their registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

68. CVS Health does substantial business in Texas and, upon information and belief, it is a pharmaceutical distributor licensed to do business in Texas. CVS Health provides pharmacy benefit management services to various health insurance entities on behalf of 90 million plan participants, including in Texas and Walker County.

69. According to the Pharmacy Benefit Management Institute, CVS Health (Caremark) was the second highest ranking PBM in 2015 with twenty-five percent (25%) of the industry market share.

70. At all times relevant hereto, CVS Health and Caremark offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that are used nationwide, including in Texas.

71. At all times relevant hereto, CVS Health, through Caremark, derives substantial revenue providing pharmacy benefits in Texas through several different means including, but not limited to, providing services and formulary to the Teacher Retirement System of Texas. At all times relevant hereto, Caremark has served as the PBM for the Texas

Association of Counties Health and Employees Benefits Pool and has reimbursed for opioids throughout Texas, including in Walker County.

72. Express Scripts Holding Company ("Express Scripts") is a pharmacy benefit manager ("PBM"), with its principal place of business in Jefferson City, Missouri, and may be served through its registered agent for service of process, CSC-Lawyers Incorporating Service Co., at 221 Bolivar Street, Jefferson City, Missouri 65101.

73. Express Scripts, Inc. is a pharmacy benefit manager ("PMB), with its principal place of business in Jefferson City, Missouri, and may be served through its registered agent for service of process, CSC-Lawyers Incorporating Service Co., at 221 Bolivar Street, Jefferson City, Missouri 65101.

74. Express Scripts Holding Company and Express Scripts, Inc. are collectively referred to as "Express Scripts." On November 15, 2011, Express Scripts and Medco Health Solutions, Inc. ("Medco") merged and formed a new holding company Aristotle Holding, Inc. ("Aristotle"). On April 2, 2012, the Federal Trade Commission ("FTC") approved the merger. Express Scripts and Medco each became a wholly-owned subsidiary of Aristotle Holding, Inc., which was renamed Express Scripts Holding Company.

75. In 2015, Express Scripts was the top ranking PBM nationwide with twenty-six percent (26%) of the industry market share.

76. Express Scripts derives substantial revenue managing pharmacy benefits in Texas through several different means. During much of the relevant period of this complaint, ESI provided services and formulary to the Teacher Retirement System of Texas.

77. Current and former employees of the Huntsville Independent School District and New Waverly Independent School District are members of the Teacher Retirement System

of Texas which means they receive their pharmacy benefits from Express Scripts and pursuant to an Express Scripts formulary. Upon information and belief, this is only one of the many ways in which Express Scripts reimburses for claims in Walker County, including opioids.

78. At all times relevant hereto, Express Scripts has operated offices throughout Texas, including in Austin and Irving, Texas. ESI publishes employment vacancies related to its Texas PBM business activities on its website.

79. Medco Health Solutions of Texas, L.L.C. is incorporated in Texas, and through its ownership structure is a Texas resident. It may be served through its registered agent for service of process, Corporation Service Company d/b/a CSC-Lawyers Inco, 211 E. 7th Street, Suite 620, Austin, TX 78701. Medco Health Solutions of Texas, L.L.C. provides pharmacy benefit management services to various health insurance entities on behalf of 83 million plan participants, including in Texas and Walker County.

80. Navitus Health Solutions, L.L.C. ("Navitus") is a pharmacy benefit manager ("PBM"), with its principal place of business in Madison, Wisconsin, and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. Navitus does substantial business in Texas and, upon information and belief, Navitus is a PBM licensed to do business in Texas. Navitus provides pharmacy benefit management services to health insurance entities on behalf of Texas plan participants, including in Walker County.

81. Navitus Holdings, LLC, is a limited liability company organized under the laws of Wisconsin with its principal place of business located in Madison Wisconsin. Navitus Holdings, LLC may be served through its registered agent: CT Corporation System, 301

South Bedford Street, Suite 1, Madison, Wisconsin 53703. Navitus Health Solutions, LLC, a pharmacy benefit manager, is a limited liability company organized under the law of Wisconsin with its principal place of business located in Madison, Wisconsin and is a wholly owned subsidiary of Navitus Holdings, LLC. Navitus Health Solutions, LLC is registered to do business in Texas (since at least 2008) and may be served in Texas through it registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

82. Navitus derives substantial revenue managing pharmacy benefits in Texas through the services it provides and the formulary it maintains in its relationships with health plans including, but not limited to, Community First Health Plans, Community Health Choice, El Paso First Health Plans, FirstCare Health Plans, Parkland Community Health Plan, and Senders Health Plans.

83. According to the Texas Medical Association "of the roughly 20 Medicaid plans operating in the state, more than half say they collectively use the same PBMs — Navitus or CVS."

84. The Navitus pharmacy directory denotes numerous pharmacies located in Walker County.

85. OptumRx, Inc. ("OptumRx") is a pharmacy benefit manager ("PBM") with its principal place in Minnetonka, Minnesota, and may be served through its registered agent for service of process, CT Corporation, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. OptumRx does substantial business in Texas and, upon information and belief, OptumRx is a PBM licensed to do business in Texas. OptumRx provides pharmacy benefit

management services to various health insurance entities on behalf of 28 million plan participants, including in Walker County.

86. OptumRx Administrative Services, LLC, is wholly owned by OptumRx, Inc., with its principal place of business in Minnetonka, Minnesota, and may be served through its registered agent for service of process, CT Corporation, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. OptumRx Administrative Services LLC is a Texas resident. OptumRx provides pharmacy benefit management services to various health insurance entities on behalf plan participants, including in Walker County.

87. Optum, Inc., is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing the subsidiaries that administer UnitedHealth's pharmacy benefits, including OptumRx, Inc. On information and belief, Optum, Inc. is a subsidiary of UnitedHealth.

88. At all times relevant hereto, OptumRx derives substantial revenue providing pharmacy benefits in Texas through several different means, including, but not limited to, providing services and formulary through the HealthSelect Prescription Drug Program for the Employee Retirement System of Texas and, for at least the years 2015-17, the Public Employee Benefits Alliance (PEBA) of Texas.

89. Prime Therapeutics LLC, ("Prime") is a pharmacy benefit manager ("PBM"), with its principal place of business in Eagan, Minnesota, and may be served through its registered agent for service of process, Corporation Service Company DBA CSC–Lawyers Incorporated, 211 E. 7th Street, Suite 620, Austin, Texas 78701. Prime is owned by seventeen Blue Cross and Blue Shield health insurance entities. Prime provides pharmacy benefit management services to those seventeen Blue Cross and Blue Shield health

insurance entities on behalf of more than 20 million plan participants, including in Texas and Walker County.

90. UnitedHealth Group, Inc. ("United") is a managed health care organization ("MCO") and pharmacy benefit manager ("PBM") with its principal place of business in Minnetonka, Minnesota and may be served through its registered agent for service of process, The Corporation Trust Company, Corporation Trust Center 1209 Orange Street, Wilmington, Delaware 19801. United operates in four segments:

a. UnitedHealthcare, which includes UnitedHealthcare Employer & Individual, UnitedHealthcare Medicare & Retirement, UnitedHealthcare Community & State, and UnitedHealthcare Global, manages networks that include 1.2 million physicians and approximately 6,500 hospitals and other facilities.

b. OptumHealth provides health management services though programs offered by employers, payers, and government entities and directly with health care delivery systems comprising more than 30,000 physicians. Optum Financial Services, through Optum Bank, a wholly-owned subsidiary, manages 4.8 million health savings accounts with over $8 billion in assets.

c. OputmInsight provides technology services and software to hospital systems, physicians, health plans, governments, and other health care entities, including to more than 100,000 physicians and 300 health plans. As of December 31, 2017, these services expected to yield $15 billion.

d. OptumRx, Inc. provides pharmacy services to more than 65 million people in the United States through a network of more than 67,000 retail pharmacies, multiple home delivery and specialty pharmacies, and home infusions service centers. In 2017 alone, OptumRx managed approximately $85 billion in pharmaceutical spending, including $35 billion in specialty pharmaceutical spending.

91. UnitedHealthcare of Texas, Inc. is a wholly-owned subsidiary of United and is a Texas resident that may be served through its registered agent for service of process, CT Corporation, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

92. United does substantial business in Texas and, upon information and belief, United is a pharmaceutical distributor licensed to do business in Texas. United distributes pharmaceuticals to retail pharmacies and institutional providers to customers nationally, including in Texas and Walker County.

93. OptumRx (UnitedHealth) was the third highest ranking PBM in 2015 with twenty-two (22%) of the industry market share.

94. Defendants are regularly engaged in the business of manufacturing, distributing, dispensing and reimbursing prescription opioids in Texas and, specifically, in Walker County. Defendants' activities in Walker County in connection with the manufacture, distribution, dispensation and reimbursement of prescription opioids was, and is, continuous and systematic, and gave rise to the causes of action alleged herein.

Preliminary Statement and Nature of the Action

95. This suit seeks recovery of damages caused by Defendants' deliberate and negligent flooding of Walker County with opioids, which resulted in Walker County residents

bearing the pain and costs of opioid addiction. To expand and maintain market shares and profits, Manufacturing Defendants deliberately misinformed doctors about the approved indications of their opioid drugs, trained doctors to misstate diagnoses so that payment would be approved for unapproved uses for these drugs, and gave kickbacks to doctors in exchange for prescribing various opioid drugs. PBM Defendants took payments from Manufacturing Defendants and ensured that opioids were widely available, even at the expense of treatments that were less addictive and more effective. Distributor Defendants and Pharmacy Defendants failed to carry out their obligations to flag and report suspicious drug sales, and otherwise failed to implement any controls over the sale and distribution of opioids. Defendants' schemes are described in more detail below.

Defendants' Fraudulent Schemes

Background

A. Opioids Are Dangerous and Ineffective

96. Due to concerns about their addictive properties, opioids have been regulated as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression" that can result from an excessive dose.

97. In fact, opioids are so addictive that most patients with more than a few weeks of opioid therapy will experience withdrawal symptoms if opioids are discontinued, commonly referred to as "dependence". Once dependent, a patient experiences deeply unpleasant symptoms when his or her current dose of opioids loses effect and is not promptly replaced with a new dose. Symptoms of opioid withdrawal include: severe

anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and others, which may persist for months after a complete withdrawal from opioids, depending on how long opioids were used.

98. Compounding the severe health issues caused by their addictive nature, when under the continuous influence of opioids over a period of time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction he or she has become accustomed to. At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction.

99. The FDA has acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects. For example, patients receiving high doses of opioids as part of long-term therapy are three to nine times more likely to suffer overdose than those on low doses. In 2013, in response to a petition to restrict the labels of long-acting opioid products, the FDA noted the "grave risks" of opioids, "the most well-known of which include addiction, overdose, and even death." The FDA further warned that "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death." The FDA required that—going forward—makers of long-acting opioid formulations clearly communicate these risks in their labels (defined to include promotional materials disseminated by or on behalf of the manufacturer of the drug). Thus, the FDA confirmed what had previously been accepted practice in the treatment of pain—that the adverse outcomes from opioid use include "addiction, unintentional overdose, and death" and that long-acting or extended release opioids "should be used ***only when alternative treatments are inadequate.***"

100. Similarly, studies have shown that between 30 percent and 40 percent of long-term users of opioids experience problems with opioid use disorders.

101. In addition to these staggering rates of addiction, it must be noted that there are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. The first random, placebo-controlled studies appeared in the 1990s, and showed only short-term efficacy for a minority of patients. A 2004 report reviewed 213 randomized, controlled trials of treatments for cancer pain and found that, while opioids had short-term efficacy, the data were insufficient to establish long-term effectiveness. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy is poor. One year later, a similar review reported poor evidence of long-term efficacy for morphine, tramadol, and oxycodone, and fair evidence for transdermal fentanyl (approved only for use for cancer pain). Endo's own research shows that patients taking opioids, as opposed to other prescription pain medicines, report higher rates of obesity (30% to 39%); insomnia (9% to 22%); and self-described fair or poor health (24% to 34%).

102. In short, despite the fact that opioids now are routinely prescribed, there never has been evidence of their safety and efficacy for long-term use. Worse, Defendants have always been aware of these gaps in knowledge and exploited them for their financial gain, including promoting opioids to treat chronic pain while both failing to disclose the lack of evidence to support their use long-term and failing to disclose the contradictory evidence that chronic opioid therapy can actually make patients worse.

B. Manufacturing Defendants Negligently and Illegally Distorted the Marketplace to Sell More Drugs

a. Off-label Marketing and Misbranding

103. Pharmaceutical drugs cannot be distributed in interstate commerce unless the manufacturer of the drug demonstrates that the drug is safe and effective for each of its intended uses. Once a drug is approved for a particular use, however, nothing prevents doctors from prescribing the drug for uses that are different than those approved. Though physicians may prescribe drugs for off-label usage, drug manufacturers are prohibited from marketing or promoting a drug for a use that is not approved, a practice known as "off-label marketing."

104. A manufacturer illegally "misbrands" a drug if the drug's labeling includes information about unapproved uses. If the manufacturer intends to promote the drug for new uses, in addition to those already approved, the materials on off-label uses must meet stringent requirements, and the manufacturer must resubmit the drug for testing and approval.

105. Manufacturing Defendants achieved larger market size, market share, and profit by promoting opioids for off-label uses. They systematically made false statements about opioid effectiveness and medical research, and designed opioid educational programs to push these false narratives.

106. For example, in 2007, Defendant Purdue and three of its executives pled guilty to misbranding in their promotion of OxyContin and agreed to pay a $634.5 million-dollar settlement to resolve a Department of Justice investigation.

107. Purdue manufactures, promotes, sells, and distributes opioids nationally, including in Texas and Walker County. Purdue's opioid drug, OxyContin, is among the most

addictive and abused prescription drugs in the history of America. Purdue promotes sales of its opioids throughout the United States, including in Texas and Walker County.

108. OxyContin is Purdue's largest-selling opioid, in both Walker County and the nation. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

109. Purdue is primarily engaged in the manufacture, promotion, and distribution of opioids nationally and in Walker County, including the following:

a. OxyContin (oxycodone hydrochloride extended release) is a Schedule II opioid agonist[1] tablet first approved in 1995 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, OxyContin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

b. MS Contin (morphine sulfate extended release) is a Schedule II opioid agonist tablet first approved in 1987 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, MS Contin was indicated for the "management of moderate

[1] An opioid agonist is a drug that activates certain opioid receptors in the brain. An antagonist, by contrast, blocks the receptor and can also be used in pain relief or to counter the effect of an opioid overdose.

to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

c. Dilaudid (hydromorphone hydrochloride) is a Schedule II opioid agonist first approved in 1984 (injection) and 1992 (oral solution and tablet) and indicated for the "management of pain in patients where an opioid analgesic is appropriate."

d. Dilaudid-HP (hydromorphone hydrochloride) is a Schedule II opioid agonist injection first approved in 1984 and indicated for the "relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief."

e. Butrans (buprenorphine) is a Schedule III opioid partial agonist transdermal patch first approved in 2010 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Butrans was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

f. Hysingla ER (hydrocodone bitrate) is a Schedule II opioid agonist tablet first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the- clock, long-term opioid treatment and for which alternative treatment options are inadequate.

g. Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) is a Schedule II combination product of oxycodone, an opioid agonist, and

naloxone, an opioid antagonist, first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

110. Manufacturing Defendants produce opioid drugs that are misbranded in violation of Texas law.[2] Manufacturing Defendants also introduced into Texas commerce drugs that are misbranded in violation of Texas law.[3] The following table contains a list of opioids and the associated Manufacturing Defendant:

Product name	Application number	Application holder
morphine sulfate extended-release	ANDA 203849	Actavis Elizabeth LLC
hydromorphone hydrochloride	ANDA 202144	Actavis Elizabeth, LLC
oxymorphone hydrochloride	ANDA 079046	Actavis Elizabeth, LLC
morphine sulfate extended-release	ANDA 079040	Actavis Elizabeth, LLC
Embeda	NDA 022321	Alpharma Pharmaceuticals LLC
fentanyl transdermal system	ANDA 077449	Aveva Drug Delivery Systems, Inc. (An Apotex Company)
Opana ER	NDA 201655	Endo Pharmaceuticals INC
Opana ER	NDA 021610	Endo Pharmaceuticals Inc
oxymorphone hydrochloride	ANDA 079087	Impax Laboratories, Inc.
Nucynta ER	NDA 200533	Janssen Pharmaceuticals INC
Duragesic	NDA 019813	Janssen Pharmaceuticals INC
Avinza	NDA 021260	King Pharmaceuticals LLC
Exalgo	NDA 021217	Mallinckrodt INC The Pharmaceuticals Business of Covidien
oxymorphone hydrochloride	ANDA 202946	Mallinckrodt Pharmaceuticals
fentanyl transdermal system	ANDA 077154	Mallinckrodt Pharmaceuticals
morphine sulfate extended-release	ANDA 076438	Mallinckrodt Pharmaceuticals
morphine sulfate extended-release	ANDA 076412	Mallinckrodt Pharmaceuticals
methadone hydrochloride	ANDA 040517	Mallinckrodt Pharmaceuticals
Methadose	ANDA 040050	Mallinckrodt Pharmaceuticals

[2] "[T]he manufacture within this state of any food, drug, device, or cosmetic that is adulterated or misbranded." TEX. FOOD, DRUG, & COSMETICS ACT § 431.021(h).

[3] "[T]he introduction or delivery for introduction into commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." TEX. FOOD, DRUG, & COSMETICS ACT § 431.021(a).

Product name	Application number	Application holder
morphine sulfate	ANDA 200824	Mylan Pharmaceuticals Inc.
fentanyl transdermal system	ANDA 076258	Mylan Technologies Inc.
morphine sulfate extended-release	ANDA 77855	Nesher Pharms
morphine sulfate extended-release	ANDA 76733	Nesher Pharms
morphine sulfate extended-release	ANDA 76720	Nesher Pharms
fentanyl transdermal system	ANDA 077775	Noven Pharmaceuticals, Inc.
hydromorphone hydrochloride extended-release	ANDA 204278	Paddock Laboratories, LLC
morphine sulfate extended-release	ANDA 200812	Par Pharmaceuticals, Inc.
oxymorphone hydrochloride	ANDA 200792	Par Pharmaceuticals, Inc.
fentanyl transdermal system	ANDA 077062	Par Pharmaceuticals, Inc.
Hysingla ER	NDA 206627	Purdue Pharma LP
Targiniq ER	NDA 205777	Purdue Pharma LP
Oxycontin	NDA 022272	Purdue Pharma LP
methadone hydrochloride	ANDA 090707	Watson Laboratories, Inc.
fentanyl transdermal system	ANDA 076709	Watson Laboratories, Inc.
Zohydro ER	NDA 202880	Zogenix INC

111. Defendant wholesalers also receive drugs that are misbranded in violation of Texas law. "[T]he receipt of a prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such a drug for payment or otherwise." TEX. FOOD, DRUG, & COSMETICS ACT § 431.021(jj).

112. The Medicaid drug rebate program is a system involving various entities such as manufacturers, wholesalers, PBMs, pharmacies, the Centers for Medicaid and Medicare Services ("CMS"), and the state Medicaid agencies. However, the system mainly relies upon a two-way interaction between manufacturers and CMS.

113. Drug manufacturers pay rebates to the states to ensure that the Medicaid program is receiving the lowest price on covered drugs. But the system has put the entire process, practically unmonitored, into the hands of the very people who abuse the system.

114. The manufacturer calculates its Medicaid rebate per unit using its lowest price ("best price"), and its average price (average manufacturer's price, or "AMP"). The manufacturer then pays the state that calculated rebate amount for each unit paid for by Medicaid. Manufacturers have exploited this rebate system by falsely reporting the correct best price and/or the correct AMP. Manufacturers have been caught reporting that false number in order to reduce their rebate liability.

b. Defendants Promoted Their Products Through Direct Marketing to Prescribers and Consumers

115. Manufacturing Defendants' direct marketing proceeded on two tracks, serving two related purposes. First, Manufacturing Defendants used branded and unbranded marketing tactics to build confidence in long-term opioid use by overstating their benefits and downplaying their risks, and thereby expand the chronic pain market. In addition, Manufacturing Defendants used sales representatives, physician speakers recruited by the sales representatives, and medical journal advertising to claim a larger share of that expanded market. Manufacturing Defendants directed all of this activity through carefully designed marketing plans that were based on extensive research into prescriber habits and the efficacy of particular sales approaches and messages.

116. Manufacturing Defendants engaged in widespread advertising campaigns touting the benefits of their drugs. Manufacturing Defendants purchased print advertisements in a broad array of medical journals that ranged from those aimed at specialists (such as the *Journal of Pain* and *Clinical Journal of Pain*), to journals with wider medical audiences (such as the *Journal of the American Medical Association*). Manufacturing Defendants' advertising budgets nearly tripled from 2001 to 2011, at which time they collectively spent

more than $14 million on medical journal advertising of opioids. The 2011 total included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

117. A number of these advertisements deceptively portrayed the benefits of opioid therapy for chronic pain. As just one example, a 2005 Purdue advertisement for OxyContin that ran in the *Journal of Pain* touted the drug as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing and proclaimed that "There Can Be Life With Relief." This depiction falsely implied that OxyContin provides both effective long-term pain relief and functional improvement, claims that, as described below, are unsubstantiated and contradicted in the medical literature.

118. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Manufacturing Defendants' messages are accurately and consistently delivered across marketing channels and in each sales territory. Manufacturing Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

119. In addition to advertising in medical journals, Manufacturing Defendants devoted massive resources to direct sales contacts with prescribers. In 2014 alone, Manufacturing Defendants collectively spent $168 million on selling opioids to physicians nationwide. This figure includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis. The total figure is more than double Manufacturing Defendants' collective spending on selling in 2000.

120. Manufacturing Defendants have spent hundreds of millions of dollars promoting their opioids through their respective sales forces because they understand that sales representatives' sales pitches are effective. Numerous studies indicate that marketing can and does impact doctors' prescribing habits, and face-to-face selling has the highest influence on prescribing. Manufacturing Defendants could see this phenomenon at work not only in the aggregate, as their sales climbed with their promotional spending, but also at the level of individual prescribers, whom they targeted for selling and who responded by prescribing more of Defendants' drugs.

121. Manufacturing Defendants guided their efforts to expand opioid prescribing through comprehensive marketing and business plans for each drug. These documents, based on the companies' extensive market research, laid out ambitious plans to bring in new prescribers and increase overall prescribing of Manufacturing Defendants' opioids.

122. Manufacturing Defendants target individual health care providers by a combination of zip code, facility, type of practice, specialty, ease of in-person access, and the potential for persuading the provider to prescribe. Manufacturing Defendants start this process with external IQVIA prescribing data and internal wholesaler chargeback data. Manufacturing Defendants then further refine their targets with input from sales representatives, which includes ease of in-person access, potential to be persuaded, the provider's desire for healthcare data, and any information on payments and inducements that the provider has accepted. There is no correlation to demonstrated need or demand for opioid therapy, or to risk of abuse.

123. Collectively, Manufacturing Defendants' marketing plans reveal dual strategies, which often operated parallel to one another. In the beginning, Manufacturing Defendants'

sales representatives continued to focus their selling efforts on pain specialists and anesthesiologists, who are the highest-volume prescribers of opioids but are also, as a group, more educated than other practitioners about opioids' risks and benefits. Seeking to develop market share and expand sales, however, Manufacturing Defendants also targeted increasing numbers and types of prescribers for marketing.

124. This expanded market of prescribers was, as a group, less informed about opioids and, market research concluded, more susceptible to Manufacturing Defendants' marketing messages. These prescribers included nurse practitioners and physician assistants. The expanded market also included internists, general practitioners, and family doctors who were low- to mid-volume prescribers.

125. Manufacturing Defendants knew that physicians were more likely to prescribe their medications when patients asked for those medications. Manufacturing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials. These took the form of pamphlets, videos, or other publications that patients could view in their physician's office, as well as employer and workers' compensation plan initiatives to, as Endo put it, "[d]rive demand for access through the employer audience by highlighting cost of disease and productivity loss."

126. Manufacturing Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons (home office clinical specialists); centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising.

127. Each Manufacturing Defendant promoted the use of opioids for chronic pain through sales representatives who visited individual physicians and their staff in their offices and facilities. Manufacturing Defendants also promoted the use of opioids for chronic pain through small group speaker programs. By establishing close relationships with doctors, Manufacturing Defendants' sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to address individual prescribers' concerns about prescribing opioids for chronic pain.

128. Manufacturing Defendants developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing volume. Manufacturing Defendants purchase and closely analyze prescription sales data from a healthcare data company called IQVIA (previously known as "IMS Health"). This data allows them to precisely track the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their sales efforts. Manufacturing Defendants also closely monitored doctors' prescribing after a sales representative's visit to allow them to refine their planning and messaging and to evaluate and compensate their sales representatives.

129. Manufacturing Defendants' sales representatives have visited hundreds of thousands of doctors, including thousands of visits to Walker County prescribers, and as described herein, spread misinformation regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. This misinformation includes deceptive and unfair claims regarding the risks of opioids for chronic pain, particularly the risks of addiction, withdrawal, and high doses, as well as the benefits.

130. Each Manufacturing Defendant carefully trained its sales representatives to deliver messages that the companies designed to generate prescriptions of that company's drugs in particular and opioids in general. Manufacturing Defendants direct and monitor their sales representatives—through detailed action plans, training, tests, scripts, role-plays, supervisor tag-alongs, and other means. These tactics were employed to ensure that individual sales representatives actually delivered the desired messages and did not veer off-script. Manufacturing Defendants require their sales representatives to deploy sales aids that were reviewed, approved, and supplied by the company. The companies forbade the sales representatives from using "homemade bread"—*i.e.*, promotional materials from any source other than the company's marketing and compliance departments. Sales representatives' adherence to their corporate training is a required component of employment. Departing from their company's approved messaging can and does lead to severe consequences, including termination of employment.

131. Besides carefully training their sales representatives, Manufacturing Defendants also used surveys of physicians—conducted by third-party research firms—to assess how well their core messages came across to prescribers. These "verbatim" recollections of sales representatives' messages are an integral tool in ensuring consistent delivery of approved messages. They also help Manufacturing Defendants gauge physicians' perceptions of, and willingness to prescribe, a particular Defendant's drugs.

132. In addition to making sales calls, Manufacturing Defendants' sales representatives also identified doctors to become paid speakers, who presented the company's sales pitch to other physicians during meals at high-priced restaurants. Manufacturing Defendants almost always select physicians who are "product loyalists." Endo, for instance, sought to

use high prescribers of its drugs as local thought leaders to market Opana ER to primary care doctors. Such invitations are lucrative to the physicians selected for these bureaus; honorarium rates range from $800 to $2,000 per program, depending on the type of event, and even speaker training typically is compensated at $500 per hour.

133. These speaker programs and associated speaker training serve three purposes: 1) they provide a financial incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; 2) they provide a forum in which to further market to the speaker; and 3) they provide an opportunity to market to the speaker's peers. Manufacturing Defendants grade their speakers, and future opportunities are based on speaking performance and product usage. Manufacturing Defendants also track the prescribing of event attendees. It would make little sense for Manufacturing Defendants to devote significant resources to programs that did not increase their sales, which is often referred to in the industry as "return on investment" or "ROI".

134. Like the sales representatives who select them, speakers are expected to stay "on message"—indeed, they agree in writing to follow the slide decks provided to them. This is important because the FDA regards promotional talks as part of product labeling and requires their submission for review. Speakers thus give the appearance of providing independent, unbiased presentations on opioids, when in fact they are presenting a script prepared by Manufacturing Defendants' marketing departments. These presentations conveyed misleading information, omitted material information, and failed to correct Manufacturing Defendants' prior misrepresentations about the risks and benefits of opioids. Although these meal-based speaker events are more expensive to host and typically have lower attendance than continuing medical education events ("CMEs"), they

are subject to less professional scrutiny and thus afford Manufacturing Defendants greater freedom in the messages they present.

135. For example, numerous executives with Defendant pharmaceutical manufacturer Insys have been indicted since 2016 for devising and fostering a scheme to bribe practitioners to write large numbers of Fentanyl Spray prescriptions, most often for patients who did not have cancer, for which the drug was indicated. The indictment states that because insurers were reluctant or unwilling to pay for the drug for patients without cancer, employees of the company were directed to call insurers directly and defraud them by lying about patient diagnoses, the type of pain being treated, and the patient's course of treatment with other medication. By bribing practitioners to write prescriptions for Fentanyl Spray and then defrauding insurers, Insys dramatically increased the volume of prescriptions written and the rate at which insurers approved payment for the drug, generating substantial profits.

136. In the Insys case, the company admitted that its payments to doctors for speaking fees or "honoraria" were for the purpose of increasing prescriptions and served as a bribe. In fact, Insys targeted prescribing physicians who were going through divorce or other financial difficulties, knowing that these doctors would be more likely to engage in the qui pro quo that Insys sought.

137. Once Insys made a connection with a prescribing physician, Insys would often provide an Insys-paid staffer to work in the physician's office with responsibility for persuading insurance companies to pay for Insys drugs, including causing insurers to believe that patients had cancer when they did not.

138. In addition to these in-person visits and speaker programs, Manufacturing Defendants sought to reach additional prescribers by expanding beyond traditional sales calls and speaker events to new channels for their messages. For their sales forces, these included marketing to prescribers through voice mail, postcards, and email—so-called "e-detailing." Manufacturing Defendants also created new platforms for their speakers by implementing "peer to peer" programs such as teleconferences and webinars that were available to prescribers nationally. These programs allowed Manufacturing Defendants to use this seemingly credible vehicle to market to hard-to-reach audiences such as prescribers at hospitals, academic centers, and other locations that limit or prohibit in-person sales calls.

139. As they did nationwide, Manufacturing Defendants extensively tracked the prescribing behavior of Walker County-area health care providers and used that data to target their sales calls and speaker recruiting efforts. Top prescribers were profiled at the city, region, zip code, and sometimes facility levels, with information about their specialty, prescribing patterns (including product and dose), product loyalty and refill history. Providers' prescribing volume was ranked and sorted into deciles.

140. Manufacturing Defendants employed the same marketing plans, strategies, and messages in and around Walker County, Texas as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Manufacturing Defendants' messages are accurately and consistently delivered across marketing channels and in each sales territory. Manufacturing Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

c. Defendants Used "Unbranded" Marketing, Manipulated Doctor Groups, and Planted Research to Increase Opioid Use.

141. In addition to their direct marketing efforts, Manufacturing Defendants used third-party marketing of opioid drugs in general ("unbranded marketing"), which they deployed as part of their national marketing strategies for their drugs. Each Manufacturing Defendant marketed their drugs by (a) employing a network of key opinion leaders ("KOLs"), doctors who were influential leaders, (b) funding and controlling third-party groups ("Front Groups") that were nominally independent but in fact served Manufacturing Defendants, and (c) planting research in medical journals that was not factually true.

142. Manufacturing Defendants' unbranded marketing created and relied upon an appearance of independence and credibility that was false and undeserved but central to its effectiveness.

143. Unlike their direct promotional activities, Manufacturing Defendants' unbranded marketing allowed them to evade the oversight of regulators and gave them greater freedom to expand their deceptive messages.

144. For example, unbranded advertising avoided regulatory scrutiny because Defendants did not have to submit it to the FDA. The results were predictable. Manufacturing Defendants' deceptive unbranded marketing often contradicted their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

a. Opana ER Advertisement (Branded): "All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use.**"

b. Pain: Opioid Therapy (Unbranded): "People who take opioids **as prescribed usually do not become addicted.**"

145. All of this unbranded marketing violated Texas and federal law. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. Under Federal law, a drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.4 Under Texas law, drug manufacturers that introduce into Texas commerce drugs that are misbranded are in violation of Texas law.

> "[T]he introduction or delivery for introduction into commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." Tex. Food, Drug, & Cosmetics Act § 431.021(a).
>
> "[T]he manufacture within this state of any food, drug, device, or cosmetic that is adulterated or misbranded." Tex. Food, Drug, & Cosmetics Act § 431.021(h).

146. Defendant wholesalers who received drugs that are misbranded are also in violation of Texas law:

> "[T]he receipt of a prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such a drug for payment or otherwise." Tex. Food, Drug, & Cosmetics Act § 431.021(jj).

147. The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand

the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients. 148.

149. Thus, Manufacturing Defendants' promotional materials (including unbranded marketing) are part of their drugs' labels and required to be accurate, balanced, and not misleading.

150. Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product's risks. "The most serious risks set forth in a product's labeling are generally material to ***any*** presentation of efficacy." The FDA notes that "[b]ecause people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included." Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive.

151. The Texas False Claims Act (Tx. Hum. Res. Code Ann. §§ 36) and the Texas Deceptive Trade Practices Act (Tx. Bus. & Com. §§ 17) reflect the same judgment that drug companies, just like other businesses, have a duty to deal honestly with consumers, government, and other payors who purchase and use their products.

152. While Texas statutes, regulations, and common law (like federal law) require that Defendant Manufacturers engage in honest marketing, in fact Defendant Manufacturers engaged in widespread schemes to promulgate false and misleading information about opioids.

153. For example, Manufacturing Defendants market through Front Groups—third parties such as organizations of scientists, physician organizations, or patient or professional organizations—that appear to be independent and therefore more credible. In the case of opioids, Manufacturing Defendants marketed through Front Groups such as the non-profit American Pain Foundation, the American Pain Society, and the American Academy of Pain Medicine. The FDA has made clear that its promotional requirements apply to both direct marketing and Front Group marketing:

> FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf. . .. . Therefore, a firm is responsible for the content generated by its employees or any agents acting on behalf of the firm who promote the firm's product. For example, if an employee or agent of a firm, such as a medical science liaison or paid speaker (e.g., a key opinion leader) acting on the firm's behalf, comments on a third-party site about the firm's product, the firm is responsible for the content its employee or agent provides. A firm is also responsible for the content on a blogger's site if the blogger is acting on behalf of the firm.

154. In addition to being carried out directly or through third parties, drug companies' promotional activity can be branded or unbranded; unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can sidestep the extensive regulatory framework.

155. Manufacturing Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These were important elements of Manufacturing Defendants' marketing plans. These plans specifically contemplated the use of KOLs and Front Groups, because they seemed independent and therefore outside of FDA oversight. Through unbranded materials, Manufacturing Defendants presented information and instructions concerning opioids that were contrary or inconsistent with information on FDA

approved marketing materials; drug labels; and Manufacturing Defendants' own knowledge of opioid risks and benefits. Manufacturing Defendants did so knowing that unbranded materials typically are not submitted to the FDA for review.

156. Once Defendant Manufacturers' unbranded messages were channeled through Front Groups, other Defendants adopted these messages as their own. Manufacturing Defendants cited to them, edited them, approved them, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. Unbranded brochures and other materials that are "disseminated by or on behalf of [the] manufacturer" constitute drug "labeling" that may not be false or misleading in any particular. Sales representatives distributed deceptive Front Group marketing materials to Manufacturing Defendants' target audiences. Manufacturing Defendants are responsible for these materials.

157. Moreover, Manufacturing Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these Front Groups, ensuring that Manufacturing Defendants were consistently aware of their content. By funding, directing, editing, and distributing these materials, Manufacturing Defendants exercised control over their deceptive messages and acted in concert[5] with these Front Groups to fraudulently promote the use of opioids for the treatment of chronic pain.

158. For example, on September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . .

[5] As used in this Petition, the allegation that Defendants "acted in concert" with third parties is intended to mean *both* that they conspired with these third parties to achieve some end and that they aided and abetted these third parties in the commission of acts necessary to achieve it.

unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products." The letter details a series of unsubstantiated, false or misleading claims regarding Duragesic's effectiveness and that "imply that patients will experience improved social or physical functioning or improved work productivity", including:

a. "'Demonstrated effectiveness in chronic back pain with additional patient benefits, . . . 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep.'"

b. "'All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain.'"

c. "'Significantly reduced nighttime awakenings.'"

d. "'Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index.'"

e. "'Significant improvement in physical functioning summary score.'"

f. "'Significant improvement in social functioning.'"

g. "'1,360 loaves . . . and counting,' '[w]ork, uninterrupted,' '[l]ife, uninterrupted,' '[g]ame, uninterrupted,' '[c]hronic pain relief that supports functionality,' '[h]elps patients think less about their pain,' and '[i]mprove[s] . . . physical and social functioning.'"

159. The Front Group publications that Manufacturing Defendants assisted in creating and distributing did not include the warnings and instructions consistent with the risks and benefits known to Manufacturing Defendants. For example, these publications either did

not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied that patients faced a serious risk of addiction.

160. By acting through Front Groups, Manufacturing Defendants were able to both avoid FDA scrutiny and give the false appearance that the messages reflected the views of independent third parties. Later, Manufacturing Defendants would cite to these sources as "independent" corroboration of their own statements. Front Group documents not only had greater credibility, but broader distribution, as doctors did not "push back" at having materials from, for example, the non-profit American Pain Foundation ("APF") on display in their offices, as they might with first-party, drug company pieces.

161. Nevertheless, the independence of these materials was a ruse—Manufacturing Defendants were in close contact with these Front Groups. Manufacturing Defendants paid for and were aware of the misleading information they were disseminating about the use of opioids to treat chronic pain, and regularly helped them to tailor and distribute their misleading, pro-opioid messaging.

162. Several representative examples of such Front Groups are highlighted below, but there are others, too, such as APS, AGS, FSMB, American Chronic Pain Association ("ACPA"), AAPM, American Society of Pain Educators ("ASPE"), NPF, and PPSG.

163. The most prominent of Manufacturing Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at $1.7 million.

164. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of

addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Walker County.

165. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Dr. Russell Portenoy (whose deep connections to Manufacturing Defendants is discussed below), explained, the lack of funding diversity was one of the biggest problems at APF.

166. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Manufacturing Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. As laid out below, APF functioned largely as an advocate for the interests of Manufacturing Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's

desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

167. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

168. APF assisted in other marketing projects for drug companies. One project funded by Defendant drug company Alpharma—*APF Reporter's Guide: Covering Pain and Its Management* (2009)—recycled text that was originally created as part of the company's training document.

169. The same drug company made general grants, but even then it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year—this would be a very good issue on which to use some of that. How does that work?"

170. The close relationship between APF and the drug company was not unique, but mirrors relationships between APF and Manufacturing Defendants. APF's clear lack of independence—in its finances, management, and mission—and its willingness to allow Manufacturing Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

171. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party and Manufacturing Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

172. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Manufacturing Defendants, issued treatment guidelines, and sponsored and hosted medical education programs essential to Manufacturing Defendants' deceptive marketing of chronic opioid therapy.

173. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

174. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Dr. Perry Fine, Dr. Russell Portenoy, and Dr. Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."

175. AAPM's staff understood they and their industry funders were engaged in a common task. Manufacturing Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

176. Like cigarette makers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Manufacturing Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively market the risks, benefits, and superiority of opioids to treat chronic pain.

177. Manufacturing Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the same language and format to disseminate the same deceptive messages. These KOLs have worked reciprocally with Manufacturing Defendants to promote misleading messaging regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and

misleading, these misstatements were nevertheless disseminated to Walker County prescribers and patients.

178. One vehicle for their collaboration was the Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Dr. Will Rowe described the Forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

179. PCF comprises representatives of opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (*e.g.*, American Academy of Pain Management, APS, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF and ACPA); and other likeminded organizations (*e.g.*, FSMB and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from Manufacturing Defendants.

180. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.[6] This Control of the REMS process was critical because a REMS that went too far in narrowing the uses or benefits of chronic opioid therapy, or highlighting its risks, would deflate Defendants' marketing efforts. The recommendations—drafted by Dr. Will Rowe of APF—claimed that opioids were "essential" to the management of pain, and that the REMS

[6] The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

"should acknowledge the importance of opioids in the management of pain and should not introduce new barriers."[7] Manufacturing Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

181. In addition to using Front Groups, Manufacturing Defendants cultivated a group of doctors who, upon information and belief, were selected and sponsored by Manufacturing Defendants solely because they favored the aggressive treatment of chronic pain with opioids. Manufacturing Defendants' support helped these doctors become respected industry experts. In return, these doctors repaid Manufacturing Defendants by touting the benefits of opioids to treat chronic pain.

182. Pro-opioid doctors have been at the hub of Manufacturing Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. They have served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, even while acknowledging the lack of evidence in support of that position. They have also served on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Manufacturing Defendants were able to exert control of each of these modalities through their KOLs.

[7] Defendants also agreed that short-acting opioids should also be included in REMS as not to disadvantage the long-acting, branded drugs.

183. In return, the association with Manufacturing Defendants provided the KOL's with money, prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community.

184. Manufacturing Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market. Manufacturing Defendants selected, funded, and elevated those doctors whose public positions were unequivocal and supportive of using opioids to treat chronic pain.[8] These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

185. Manufacturing Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, Manufacturing Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy, in contrast to the FDA requirement of balanced promotion. Indeed, one prominent KOL sponsored by Defendants, Dr. Portenoy, stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding. Some KOLs have even gone on to become direct employees and executives of Manufacturing Defendants, like Dr. Haddox, Purdue's Vice President of Risk Management, or Dr. Galer, Endo's former Chief Medical Officer.

186. Manufacturing Defendants provided substantial opportunities for KOLs to participate in research studies on topics Manufacturing Defendants suggested or chose,

[8] Opioid makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

with the predictable effect of ensuring that many favorable studies appeared in the academic literature. As described by Dr. Portenoy, drug companies would approach him with a study that was well underway and ask if he would serve as the study's author. Dr. Portenoy regularly agreed.

187. Manufacturing Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, typically over meals or at conferences. From 2000 on, Cephalon, for instance, has paid doctors more than $4.5 million for programs relating to its opioids.

188. These KOLs were carefully vetted to ensure that they were likely to remain on-message and supportive of a Manufacturing Defendant's agenda. One measure was a doctor's prior work for trusted Front Groups.

189. Manufacturing Defendants kept close tabs on the content of the misleading materials published by these KOLs. They also scripted what these KOLs said. The KOLs knew or deliberately ignored the misleading way in which they portrayed the use of opioids to treat chronic pain to patients and prescribers, but they continued to publish those misstatements to benefit themselves and Manufacturing Defendants, all the while causing harm to Walker County prescribers and patients.

190. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL who Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

191. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of APF, an advocacy organization almost entirely funded by Defendants.

192. Dr. Portenoy also made frequent media appearances promoting misrepresentations about opioids. He appeared on *Good Morning America* in 2010 to discuss the long-term use of opioids for chronic pain. On this widely watched program, broadcast in Walker County and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."

193. To his credit, Dr. Portenoy has recently admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist." Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."

194. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah.

Dr. Webster was President in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy.[9] He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $9 million from Pfizer, Mallinckrodt, Bristol-Myers Squibb, Jazz Pharmaceuticals, Orexo US, and Cephalon).

195. Dr. Webster had been under investigation for overprescribing by the DEA, which raided his clinic in 2010. More than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk.* Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach Walker County doctors.

[9] Journal supplements are paid for by drug manufacturers and, although they may be designed to blend into the rest of the journal, are not peer-reviewed and constitute drug company advertising.

196. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."

197. Rather than find a way to actually test the safety and efficacy of opioids for long-term use, Manufacturing Defendants led everyone to believe that they already had. Manufacturing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to shape the perceptions of prescribers, patients and payors. This literature was, in fact, marketing material focused on persuading doctors and consumers that the benefits of long-term opioid use outweighed the risks.

198. To accomplish this, Manufacturing Defendants—sometimes through third-party consultants and/or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

199. Manufacturing Defendants coordinated the timing and publication of manuscripts, abstracts, posters/oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs. The plans for these

materials did not originate in the departments within the organizations that were responsible for research, development or any other area that would have specialized knowledge about the drugs and their effects on patients. Instead, they originated in Manufacturing Defendants' marketing departments and with Manufacturing Defendants' marketing and public relations consultants (also known as ad agencies). Manufacturing Defendants often relied on "data on file" or presented posters, neither of which are subject to peer review. They also published their articles not through a competitive process, but in paid journal supplements, which allowed Manufacturing Defendants to publish, in nationally circulated journals, studies supportive of their drugs.

200. Manufacturing Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even where references distorted the significance or meaning of the underlying study. Most notably, Purdue promoted a 1980 reference in the well-respected *New England Journal of Medicine*: J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J. Med.* 123 (1980) ("Porter-Jick Letter"). It is cited 856 times in Google Scholar, and 86 times since 2010. It appears as a reference in two CME programs in 2012 sponsored by Purdue and Endo. Defendants and those acting on their behalf failed to reveal that this "article" is actually a letter-to-the-editor, not a peer-reviewed study (or any kind of study at all). The Porter-Jick Letter, describes a review of the charts of hospitalized patients who had received opioids. Because it was a 1980 study, standards of care almost certainly would have limited opioids to acute or end-of-life situations, not chronic pain.

201. The Porter-Jick Letter notes that, when these patients' records were reviewed, it found almost no references to signs of addiction, though there is no indication that

caregivers were instructed to assess or document signs of addiction. None of these serious limitations is disclosed when Manufacturing Defendants or those acting on their behalf cite the Porter-Jick Letter, typically as the sole scientific support for the proposition that opioids are rarely addictive, even when taken long-term. In fact, Dr. Jick later complained that his letter had been distorted and misused.

202. Manufacturing Defendants worked not only to create or elevate favorable studies in the literature, but to discredit or bury negative information. Manufacturing Defendants' studies and articles often targeted articles that contradicted Defendants' claims or raised concerns about chronic opioid therapy. In order to do so, Manufacturing Defendants—often with the help of third-party consultants—targeted a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

203. Manufacturing Defendants' strategies—first, to plant and promote supportive literature and then, to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicts those claims—are flatly inconsistent with their legal obligations. The strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief and distorted prescribing patterns as a result.

204. As a result of Manufacturing Defendants' wrongful conduct, the number of prescriptions for opioids increased sharply, reaching over 250 million prescriptions in 2012, almost enough for every person in the United States to have a bottle of pills. This represents an increase of three hundred percent (300%) since 1999.

d. Treatment Guidelines

205. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Manufacturing Defendants, who are otherwise not experts, nor trained, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications.

206. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that are FSMB members have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Manufacturing Defendants.

207. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which FSMB admitted was produced "in collaboration with pharmaceutical companies." The FSMB Guidelines taught not that opioids could be appropriate in limited cases or after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option. The FSMB Guidelines failed to mention risks relating to respiratory depression and overdose, and they discussed addiction only in the sense that "inadequate understandings" of addiction can lead to "inadequate pain control."

208. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from the 2004 guidelines, *Responsible Opioid Prescribing*, also make these same claims. These

guidelines were posted online and were available to and intended to reach Walker County physicians.

209. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Cephalon, Endo, and Purdue. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies, including Endo and Cephalon, for bulk sales and distribution to sales representatives for distribution to prescribing doctors.

210. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards (and through the boards, to practicing doctors), and the FSMB benefitted by earning approximately $250,000 in revenue and commissions from their sale. The FSMB website describes the book as the "leading continuing medication education (CME) activity for prescribers of opioid medications."

211. Drug companies relied on FSMB guidelines to convey the message that "undertreatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head—doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught that they would be punished instead if they failed to prescribe opioids to their patients with pain.

212. The 2012 revision of *Responsible Opioid Prescribing* continues to teach that pseudoaddiction is real and that opioid addiction risk can be managed through simple risk screening.

213. AAPM and the APS are professional medical societies, each of which received substantial funding from Manufacturing Defendants from 2009 to 2013 (with AAPM receiving over $2 million). They issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement, which also formed the foundation of the FSMB Guidelines, remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.

214. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the twenty-one panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

215. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and

have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Walker County during the relevant time period, and are still available online, and were reprinted in the *Journal of Pain.*

216. Manufacturing Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

217. The American Geriatrics Society ("AGS"), a nonprofit organization serving health care professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter "2009 AGS Guidelines"). The 2009 AGS Guidelines included the following recommendations: "All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

218. AGS contracted with Defendants Endo, Purdue, and Janssen to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. These Defendants were aware of the content of the 2009 Guidelines when they agreed to provide funding for these projects. The 2009 Guidelines were released at the May 2009 AGS Annual Scientific Meeting in Chicago and first published online on July 2, 2009. AGS submitted grant requests to

Defendants including Endo and Purdue beginning July 15, 2009. Internal AGS discussions in August 2009 reveal that it did not want to receive up-front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed, and allowing these companies to determine whether to provide support only after they have approved the message, AGS ceded significant control to these companies. Endo, Janssen, and Purdue all agreed to provide support to distribute the guidelines.

219. AGS has received $344,000 in funding from opioid makers since 2009. Five of ten of the experts on the guidelines panel disclosed financial ties to Manufacturing Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Manufacturing Defendants, receiving grants from Manufacturing Defendants, and investing in Manufacturing Defendants' stock. The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

220. The extent of Manufacturing Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines—the authors of which did not accept drug company funding—reached very different conclusions. The 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in

fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."

221. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.

222. The *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their review:

> revealed the lack of solid evidence-based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps . . . include: lack of effectiveness studies on long-term benefits and harms of opioids . . .; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification . . .; lack of evidence on the utility of informed consent and opioid management plans . . .; and treatment of patients with chronic non-cancer pain at higher risk for drug abuse or misuse.

e. **Continuing Medical Education**

223. CMEs are ongoing professional education programs provided to doctors and healthcare professionals. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are delivered by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

224. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. Manufacturing Defendants aimed to reach general practitioners, whose broad area of focus and lack of specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Manufacturing Defendants' deceptions.

225. In all, Manufacturing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

226. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions

in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."

227. Dozens of CMEs that were available to and attended or reviewed by Walker County doctors during the relevant time period did not live up to the AMA's standards.

228. The influence of Manufacturing Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages remembered by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times. Students who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non-industry-funded CME mentioned the risks of death and addiction much more frequently than the other group. Neither group could accurately identify whether the article they read was industry- funded, making clear the difficulty health care providers have in screening and accounting for source bias.

229. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, Manufacturing Defendants could expect messages to be favorable to them, as these organizations were otherwise dependent on Manufacturing Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Defendants measured the effects of CMEs on prescribers' views on opioids and their

absorption of specific messages, confirming the strategic marketing purpose in supporting them.

f. Unbranded Patient Education

230. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats." Evidence also demonstrates that physicians are willing to acquiesce to patient demands for a particular drug— even for opioids and for conditions for which they are not generally recommended. Recognizing this fact, Manufacturing Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

231. The drug companies expect that they will recoup their investment in direct-to-consumer advertisements because they will capture at least some of any additional prescriptions that result from patients "asking their doctor" about drugs that can treat their pain. Doctors also may review direct-to-consumer materials sales representatives give them to distribute to patients.

C. PBMs: Promoted Opioid Use Instead of Alternatives So PBMs Could Receive Rebates from Manufacturer Defendants and Higher Fees

232. PBM Defendants act as an intermediary between drug manufacturers, on the one hand, and patients, on the other hand. Over and over again, PBM Defendants set aside the interests of patients and worked with drug manufacturers to ensure that opioids were prescribed and used in massive and dangerous quantities.

233. PBMs offer a wide range of services to prescription drug manufacturers and healthcare providers. PBMs manage prescription drug benefits for healthcare plans by providing services such as adjudication of claims, mail order of prescription drugs to plan beneficiaries, administrative services, and rebate and discount negotiations with drug manufacturers. When a PBM negotiates price discounts, disease management programs, and rebates with drug manufacturers, it must not solicit or accept improper payments from manufacturers in return for favoring a particular drug over another.

234. PBMs are agents between payers (representing patients), drug manufacturers, and retailers and they influence which drug products are used most frequently and set prices for pharmacies. The PBMs create or establish formularies. A formulary is a list of drugs and drug equivalents the payer will reimburse for. The PBMs develop these formularies in conjunction with their clients. Clients can utilize a standard PBM formulary, or create a custom formulary, or customize a standard formulary at their discretion. The formularies are ultimately controlled by the payers.

235. The greater the number of claims that are adjudicated by PBMs, the greater the revenue generated for the PBM. This gives a PBM incentive to not institute or recommend a program to reduce opioid prescriptions. PBMs with their clinical expertise and data resources should have recommended to their clients and instituted programs to prevent abuse. PBMs should have done this all along, but are, only now, starting to roll these anti-abuse programs out.

236. PBMs are a necessary party to any discussion of opioid-related misconduct committed by pharmaceutical supply chain actors, and its ramifications. Neither courts nor the governmental entities left to clean up the opioid crisis can address the flow of opioids

or the costs of abatement without including the parties that are in fact capable of implementing client-directed controls of that flow, across all manufacturers and distributors, i.e. the PBMs. In essence, PBMs are the gatekeepers to the vast majority of opioid prescriptions filled in the United States.

237. PBMs became an even greater integral part of the pharmaceutical supply chain—that is, the path a drug takes from the manufacturing facility to a bathroom medicine cabinet—following the passage of the Medicare Modernization Act in 2003.

238. Because PBMs are the intermediary between drug manufacturers, pharmacies, and ultimately patients, these companies influence everything from pharmacy reimbursements, to what drugs are covered under formularies. In these ways, the PBMs affect which drugs enter the marketplace. Their fingerprints are on nearly every opioid prescription filled and they profit in myriad ways on every pill.

239. Caremark, Express Scripts, and OptumRx (all named PBM Defendants here) manage the drug benefits for approximately ninety-five percent (95%) of the United States' population with prescription drug coverage or 253 million American lives.

240. PBM Defendants implement drug formularies which set the criteria and terms under which pharmaceutical drugs are dispensed. In this way, PBM Defendants control prescription drug utilization overall.

241. PBM Defendants' complicity in the overall fraudulent scheme is purposeful given the nature of the financial arrangements between these Defendants and drug manufacturers and others in the supply chain. Drug manufacturers compete for PBM formulary placement (preferred placement results in greater utilization and greater profits) and pay PBM

Defendants incentives to avoid pre-authorization requirements that would reduce drug sales.

242. PBM Defendants require, and receive, incentives from the Manufacturer Defendants to keep certain drugs on formularies. These incentives include the payment of rebates by Manufacturer Defendants to PBM Defendants based on utilization, bonuses for hitting volume targets, and the payment of administrative fees. Much of this activity is not transparent to anyone, including those who in good faith hire PBM Defendants to manage their benefits.

243. PBM Defendants not only control the majority of this country's prescriptions through their formularies, they generate massive profits from that work. Nearly one third of all expenditures on branded drugs in 2015 were eventually rebated back. And, most of these rebates directly benefited PBM Defendants.

244. The big three PBMs manage the drug benefits for nearly 95% of the population that has a drug benefit plan. They control which drugs are covered by virtually all health insurance providers for over 260 million people. PBMs made almost $260 billion last year. In 2015 they covered most of the four billion retail prescriptions that were covered in the United States.

245. PBM influence is notable especially considering the lack of competitors in the PBM space. Market concentration is an important indicator of a company's ability to earn extraordinary returns, and several segments in the United States pharmaceutical distribution system are highly concentrated.

246. With this kind of oligopolistic structure, the top three PBMs have almost exclusive control over the dissemination of opioids. In concert with drug manufacturers who give

them rebates as an incentive, they recommend which drugs will be on a health insurance company's formulary, thus determining which drugs will be covered. If an insurance plan does not cover a drug, that drug will not enter the marketplace to be abused.

247. People with chronic pain are at the mercy of this system, yet the formularies enforced by the PBM Defendants on behalf of payers make it more difficult to get pain medication that is less addictive and easier to get opioids, because opioids are older, often generic, and generally cheaper than newer non-opioid alternatives. Of 35.7 million people on Medicare prescription drug plans in the second quarter of 2017, only one-third of them had access to pain medication less addictive than opioids.

248. The seeds of the opioid epidemic were sown with early over-prescription of OxyContin. In 2001, when officials in the West Virginia state employee health plan tried to get Purdue, which manufactured OxyContin, to take steps to require the pre-authorization for OxyContin, Purdue refused. Using the financial quid pro quo it had with the state's PBM, Purdue offered price-reductions in the form of rebates to Merck Medco (now Express Scripts) to try to prevent insurers from limiting access to the drug (i.e., through prior authorization):

> The strategy to pay Merck Medco extended to other big pharmacy benefit managers and to many other states, according to a former Purdue official responsible for ensuring favorable treatment for OxyContin. The payments were in the form of "rebates" paid by Purdue to the companies. In return, the pharmacy benefit managers agreed to make the drug available without prior authorization and with low copayments.
>
> "That was a national contract," Bernadette Katsur, the former Purdue official, who negotiated contracts with pharmacy benefit managers, said in an interview. "We would negotiate a certain rebate percentage for keeping it on a certain tier related to copay or whether it has prior authorization. We like to keep prior authorization off of any drug."

249. PBM Defendants are driving patients to opioids, away from abuse-deterrent form ("ADF") and less addictive forms of opiates through formulary and pricing strategies.

250. PBM Defendants make it more difficult to obtain ADF opioids. These pills are more difficult to physically alter (crushing to snort or dissolving to inject) and therefore are less prone to abuse. The three major PBMs carry at most 3 of the 10 FDA approved ADF opioids, while CVS Caremark, which has nearly 90 million members, carries none. A study by Tufts CSSD found that ninety-six percent (96%) of all prescription opioids were non-ADF in 2015.

251. The Institute for Clinical and Economic Review, a private organization funded in part by some of the largest health plans and PBMs, claimed that ADF opioids provided neither financial or societal benefits, even though they were given data showing that ADF OxyContin could prevent 4,300 cases of abuse and save $300 million over a five-year period.

> ICER ignored research that demonstrated abuse deterrent Oxy reduced abuse by 20 percent and reduced the average daily dose of OxyContin from 80mg to 60mg. Perhaps even more important, it reduced sharing and selling of the drug for getting high ("diversion") by nearly 90 percent. The diversion of generic painkillers is responsible for as many as 63 percent of fatal prescription drug overdoses. ICER consciously decided to ignore the human cost of this deadly behavior.
>
> What the ICER report ignores entirely is that one of the factors driving abuse and addiction is the inappropriate use of generic opioids for conditions that have non-opioid, on-label options. Fifty-two percent of patients diagnosed with osteoarthritis receive an opioid pain medicine as first-line treatment, as do 43 percent of patients diagnosed with fibromyalgia and 42 percent of patients with diabetic peripheral neuropathy.

252. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Many abusers start with legitimate prescriptions. For these reasons, the CDC concluded that

efforts to rein in the prescribing of opioids for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

253. The PBM Defendants' role in distributing drugs played a critical part in the current opioid epidemic.

254. There are steps the PBM Defendants could have taken in the past. They could have made it easier to access other non-addictive forms of pain relief. They could have required doctors to start treating pain first with non-opioid pain medications (otherwise known as "step therapy"), as recommended by the CDC and turn to opioids as a last resort. They could have covered alternative, non-medication treatments for pain.

255. One former Purdue Pharma official who negotiated contracts with PBMs stated, "We would negotiate a certain rebate percentage for keeping it [OxyContin] on a certain tier related to copay or whether it has prior authorization. We like to keep prior authorization off of any drug." An investigation and review of 2009 West Virginia court records that were unsealed by a state judge showed that Purdue was paying the Merck-Medco PBM in a quid pro quo arrangement to ensure that insurers were unable to limit the number of prescriptions for OxyContin. The former Purdue official stated that Purdue rebate payments to PBMs nationally were made in return for the agreement of the PBMs to make OxyContin available without insurance prior authorization restrictions and with low co-payments, which ensures that OxyContin sales would achieve blockbuster status of $3 billion per year in sales.

256. Purdue's payments of quid pro quo rebates also had the effect of ensuring that OxyContin had favorable status on PBM listings of approved drugs. These lists have tiers, some of which are more restrictive and require that the patient pay higher co-pays. Purdue

worked to ensure through its payments that OxyContin would be placed on the least restrictive tiers of these PBM drug lists. Purdue and other manufacturers made quid pro quo payments to PBMs to distribute OxyContin and other opioid drugs at a much higher volume in Texas, including in Walker County.

257. In one case reported on in the New York Times, OptumRx, which is owned by UnitedHealth, suggested that a member taking the pain drug Butrans consider switching to a "lower cost alternative," such as OxyContin or extended-release morphine, according to a letter provided by the member. Mr. Wiggin, the UnitedHealthcare spokesman, said the company's rules and preferred drug list "are designed to ensure members have access to drugs they need for acute situations, such as post-surgical care or serious injury, or ongoing cancer treatment and end of life care, as well as for long-term use after alternatives are tried."

258. According to the article, "UnitedHealthcare places morphine on its lowest-cost drug coverage tier with no prior permission required, while in many cases excluding Butrans. And it places Lyrica, a non-opioid, brand-name drug that treats nerve pain, on its most expensive tier, requiring patients to try other drugs first."

259. PBM Defendants have extensive data of prescription usage, and yet there is little evidence that they went to their customers and advised them to restrict the sales of opioids. For example, Express Scripts, the largest PBM organization in the United States with over $100 billion in revenues in 2016, tracked the consistently high use of opioids for years through its annual Drug Trend Reports. In 2006, Express Scripts reported that 17.6% of its members had used pain medication during the year. In 2009, Express Scripts reported that 18% of its members had used pain medication during the year, and that four opioid

drugs represented 65% of the use for the drug class. By 2012, the number of Express Scripts members using pain medication had increased to 18.2%, and the top four opioids represented 66.1% of the prescriptions.

260. Express Scripts ultimately announced a program called Advanced Opioid Management on June 7, 2017, many years after prescription opioid abuse had spiraled out of control. The program was based on data and abuse prevention methods that were easily available to Express Scripts all along, however the company never took any taken action to prevent abuse in this way before. The program features included "add[ing] novel opioid management features addressing other points on the care continuum, from safe disposal, to tools for physicians at the point of care and safety checks for dispensing pharmacies," all of which were easily within reach of the company for many years. Express Scripts now touts the effects of the Advanced Opioid Management program in 2018 as resulting in a "60% lower average day supply per claim (down from 18.6 days to 7.5) ... [with] 95.9% of reprocessed scripts to be 7 days' supply or less"—all reductions that could have, and should have, been achieved many years prior to save countless thousands of lives from abuse and death.

261. Other PBM Defendants have also suddenly developed opioid "abuse management" programs within the last year, using mitigation actions they could have been employing all along to stop opioids from being delivered to abusers. For example, CVS Caremark PBM announced a program on September 21, 2017 to roll out "an enhanced opioid utilization management approach" which would "include limiting to seven days the supply of opioids dispensed for certain acute prescriptions for patients who are new to therapy; limiting the daily dosage of opioids dispensed based on the strength of the opioid; and requiring the use

of immediate-release formulations of opioids before extended-release opioids are dispensed" —all actions that could have been taken many years before in order to prevent abuse and death.

262. In another example, on August 22, 2017, Defendant PBM OptumRx announced an Opioid Risk Management program which was having good initial success—reducing the number of first-fill prescriptions with greater than the maximum 7-day supply by 65%; and reducing the number of first-fill prescriptions with excessive opioid dosage by 82%.

263. Yet again, the PBM Defendants all had the data required to take these actions years ago.

264. Another source of drugs were large quantities of free drugs shipped directly to patients from manufacturers through Patient Assistance Programs ("PAP"). The PAP programs supplied free drugs to patients through third party pharmacies, primarily through PBMs. The typical guidelines are that the patient not meet the eligibility requirements for Medicaid and have an income that is no greater than 300% of the federal poverty guidelines. Patients who meet these requirements receive their drugs for free. The primary concern about PAP programs for opioid drugs would be the high risk that the opioid prescriptions could be diverted. Many patients on this program received exorbitantly high doses of the products, and the prescriptions were written for use as a medication given "as needed", or "PRN", instead of as part of a scheduled drug administration [Latin "*pro re nata*" – as needed]. The fact that large supplies that were being shipped directly to the patients increased the risk of diversion and/or abuse.

D. Pharmacies and Specialty Pharmacies: Filled Prescriptions That Were Not Necessary

265. Pharmacies and pharmacists have repeatedly dispensed opioids without a valid medical purpose and dispensed drugs that were not within the course of the pharmacies' professional practice in violation of Tex. Health & Safety Code § 481.071(a)(A). For example, on April 2, 2018, the US Drug Enforcement Agency ("DEA") announced actions from an investigation of 80 million transaction reports related to prescribers and pharmacies that dispensed disproportionately large amounts of drugs, particularly opioid drugs. The investigations led to 28 arrests, 147 revoked registrations, and 283 administrative enforcement actions. The DEA found suspicious orders and illicit diversion of dangerous pharmaceuticals.

266. Manufacturing Defendants introduced these misbranded drugs into commerce in Texas in violation of Texas law: "[T]he introduction or delivery for introduction into commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."[10]

267. PBM Defendants and/or Pharmacy Defendants received and dispensed these misbranded drugs in violation of Texas law: "[T]he receipt of a prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such a drug for payment or otherwise." Tex. Food, Drug, & Cosmetics Act § 431.021(jj).

268. Pharmacy Defendants have dispensed prescriptions for opioids despite knowing that the prescription was invalid or that the prescription was issued without a valid patient-practitioner relationship in violation of Texas law. For example, on May 26, 2017, the US Dept. of Justice announced the sentencing of the owner of GenPharm Pharmacy in Desoto, Texas for filling prescriptions for more than 70,000 30mg oxycodone pills based on

[10] TEX. FOOD, DRUG, & COS. ACT § 431.021(a).

illegitimate prescriptions. The pharmacist had filled the prescriptions for a McAllen, Texas Medical Clinic and physician, who wrote or signed the prescriptions "without conducting medical exams of patients, without determining there was a legitimate medical purpose for the prescription, and outside the usual course of professional practice". Such actions by a pharmacist violate Texas laws which prohibit them to "dispense or deliver a controlled substance or cause a controlled substance to be dispensed or delivered under the pharmacist's direction or supervision except under a valid prescription and in the course of professional practice." Tex. Health & Safety Code § 481.074(a)(1). A pharmacist also may not "dispense a controlled substance if the pharmacist knows or should have known that the prescription was issued without a valid patient-practitioner relationship." Tex. Health & Safety Code § 481.074(a)(2).

E. Distributers: Flooded the Market with Opioids While Failing to Monitor and Report Suspicious Orders

269. Prescription drug manufacturers, wholesalers/distributors and pharmacy benefit managers ("PBMs") have created this epidemic. The manufacturers make the opioids and lie about their efficacy and addictive properties. The wholesalers distribute the opioids from the manufacturer to the pharmacy. And the PBMs control, through their formularies, which drugs go where and how they are paid for.

270. Wholesale distributors, such as the Distributor Defendants, could have and should have been able to stem the excess flow of opioids into Texas and Walker County, but they did not. Distributor Defendants purchase prescription opioids from drug manufacturers and sell the opioids to hospitals, pharmacies, doctors, and other healthcare providers who then dispense the drugs to patients. Distributors are required by federal and state law to control and report unlawful drug diversions. The Distributor Defendants purposefully

ignored these responsibilities, lobbied for higher reporting thresholds and pocketed profits at the expense of Walker County. Manufacturers and the largest wholesale distributors spent $102 million from 2014–2016 to lobby Congress on the Ensuring Patient Access and Effective Drug Enforcement Act and other bills, in order to make it nearly impossible for the Drug Enforcement Agency to "freeze suspicious narcotic shipments from the companies... That powerful tool had allowed the agency to immediately prevent drugs from reaching the street."

271. The Distributor Defendants purchased opioids from manufacturers, such as the Manufacturer Defendants, and sold them to pharmacies throughout Texas, including in Walker County. The Distributor Defendants played an integral role in opioids being distributed across Texas, including Walker County.

272. The failure of all Distributor Defendants to effectively monitor and report suspicious orders of prescription opioids and to implement measures to prevent the filling of invalid and medically unnecessary prescriptions greatly contributed to the vast increase in opioid overuse and addiction. Distributor Defendants' conduct thus directly caused a public-health and law-enforcement crisis across this country, including in Walker County.

273. Distributor and Manufacturing Defendants knowingly, recklessly, and/or negligently supplied suspicious quantities of prescription opioids to obviously suspicious physicians and pharmacies in and around Walker County, without disclosing suspicious orders as required by regulations and otherwise circumventing their obligations.

274. Distributor and Manufacturing Defendants' refusal to report and investigate suspicious orders had far-reaching effects. The DEA is required to annually set production quotas for regulated drugs. In the context of opioids, however, the DEA has cited the

difficulty of determining an appropriate production level to ensuring that adequate quantities are available for legitimate medical use. That is because there are no direct measures available to establish legitimate medical need. The DEA's difficulty in setting production quotas was compounded by the fact that the Manufacturer and Distributor Defendants failed to report suspicious orders of opioids and failed to maintain effective controls against diversion. Defendants' deliberate failures thus prevented the DEA from realizing the full extent of opioid diversion for years.

275. Manufacturing and Distributor Defendants could have (and should have) reported and stopped the flow of prescription opioids into the black market. But Defendants intentionally, recklessly, and/or negligently failed to investigate, report, and halt suspicious orders. Accordingly, as a direct result of Defendants' misconduct, substantial and dangerous quantities of prescription opioids were illegally diverted to and overprescribed in Walker County.

276. "A person who is engaged in the wholesale distribution of a prescription drug, including a repackager but excluding the original manufacturer, shall provide a pedigree for each prescription drug for human consumption that leaves or at any time has left the normal distribution channel and is sold, traded, or transferred to any other person. Tex. Food, Drug, & Cosmetics Act § 431.412; Tex. Health & Safety Code § 481.067(a)-(c).

277. The Distributor Defendants also distributed controlled substances to pharmacies when they should have known they were not in the course of the pharmacists' professional practice. A pharmacist may not "dispense or deliver a controlled substance or cause a controlled substance to be dispensed or delivered under the pharmacist's direction or supervision except under a valid prescription and in the course of professional practice."

Tex. Health & Safety Code § 481.074(a)(1). The pharmacist should flag historical information and flag suspicious orders based upon historical data on the physician and patient. The wholesalers should note and take exception to too high of orders, based on the wholesalers' own data and knowledge of utilization volume and logistics (size and activity of that pharmacy and local population), that if the volume increased by a remarkable amount, the wholesaler should have known. Because of their knowledge of current and historical data, the Distributor Defendants should have known that certain customers were not in the course of professional practice, based upon their knowledge of that pharmacist's professional practices. The Distributor Defendants know how much they should have been buying, and know the size of the town – they have the data. They should have known that some were distributing far more than necessary.

278. For example, the Drug Enforcement Administration recently suspended opioid sales by a Louisiana wholesale distributor for failing to "'properly identify large suspicious orders for controlled substances sold to independent pharmacies,' in some cases sending out six times a drugstore's normal order without notifying federal drug officials as required by law'. Congress is currently investigating the three largest distribution companies (and Defendants in this case) – McKesson, AmerisourceBergen, and Cardinal Health – for "years of sales that sent hundreds of millions of pills to pharmacies across West Virginia. In some cases, millions of pills went to tiny pharmacies in small towns that could not have supported that commerce through legal purchases".

279. Distributor Defendants also distributed drugs that were misbranded, which is a violation of Texas law: "[T]he introduction or delivery for introduction into commerce of

any food, drug, device, or cosmetic that is adulterated or misbranded." Tex. Food, Drug, & Cosmetics Act § 431.021(a).

280. Distributor Defendants also received drugs that were misbranded, which is a violation of Texas law: "[T]he receipt of a prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such a drug for payment or otherwise." Tex. Food, Drug, & Cosmetics Act § 431.021(jj).

F. Allegations Applicable to all Defendants

281. The widespread use of opioid drugs is the direct result of a concerted industry scheme that has evolved over the past two decades. The Defendants and their affiliates successfully created a market for these products by identifying and expanding new markets for these products, relying on false science, which was frequently the work of their own KOL "product champions"; enlisting either unwitting or complicit healthcare providers as their advocates and accomplices; saturating the direct to consumer market with false advertising, promotions, and reassuring messages, all of which were calculated to cause and did cause consumers in Walker County to seek out these medications. In short, these Defendants expanded the market for opioids beyond that for which it was originally intended and created a crisis the likes of which has never been seen in the pharmaceutical industry.

282. These Defendants successfully created and nurtured an environment in which opioid abuse was a virtual certainty. By spending millions of dollars to convince the populace that they needed and would benefit from the use of Defendants' opioid drugs, these tortfeasors produced a network of drug distributors, dispensers and prescribers who

preyed upon a generation of dependent drug users and abusers who believed their physical ailments were being appropriately treated by the Defendants' prescription drugs. It came to pass, unfortunately, that the Defendants' primary success was in constructing a population of citizens whose initial use of opioids was legal and legitimate but was transformed into an addiction that often could be fulfilled only by the use of illegal street drugs.

283. The societal impact of controlled prescription drug diversion and abuse is considerable. Violent and property crime associated with drug diversion and abuse has increased in all regions of the United States over the past 5 years, according to the National Drug Intelligence Center (NDIC) National Drug Threat Survey. On a broader scale, the Centers for Disease Control and Prevention estimates that the total "economic burden" of prescription opioid misuse alone in the United States is $78 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.

284. The abuse of prescription opioids has contributed to another unfortunate, but foreseeable, phenomenon: the increase in the use of "recreational" opioids, particularly heroin. Many patients who are prescribed opioids for medical purposes become addicted and believe they have no alternative but to tum to illegal opioids. The inevitable result of this drastic increase in the use of heroin has been a commensurate increase in heroin-related deaths, as with other opioids. According to the Walker County Sheriff's office, "There are approximately 900 deaths a year in Walker County and the number of deaths from prescription drug overdose are proportionally greater than that of Murder, Suicide, or traffic accident fatalities."

285. This is a significant concern in Walker County, Texas, where the Sheriff's office has stated that "It has been astounding to discover through the investigations, the magnitude of narcotics abuse via prescriptions going on in all areas of our communities. It has also been astounding to discover that sometimes a very small number of Doctors are facilitating this abuse and to also discover just how much the law enforcement system cannot do to these doctors because of red tape. Investigations such as these require the help of Federal agencies such as the Drug Enforcement Administration (DEA). You can ask almost any pill pusher or pill user which doctors they all use to get their pills and when the same names come up time and time again, year after year, you will understand why we are concerned. The amount of time and attention required to investigate this abuse is substantial. On average, the Walker County Sheriff's Office arrests approximately 80 to 100 people a year for prescription drug abuse."

286. The pandemic caused by the collective actions of the Defendants has also impacted the most innocent members of society – our children. Use of opioid pain relievers increased among all populations, including women of reproductive age and pregnant women. A recent CDC report found that nearly a third of women of reproductive age were prescribed an opioid in the previous year. Since 2000, there has been a dramatic increase in the rates of opioid use disorder among pregnant women and the number of newborns diagnosed with opioid withdrawal after birth, known as neonatal abstinence syndrome (NAS). In 2012 alone, one child was born every 25 minutes with neonatal abstinence syndrome. Not only is this condition traumatic for the child and the family, it poses a prohibitive financial burden on the residents of Walker County. The costs of treating children diagnosed with NAS are exponentially higher than the costs associated with newborns not affected with

NAS: an average of $66,700 compared to $3,500. Additionally, the long-term outcomes of the neonatal abstinence syndrome are difficult to predict, but likely include adverse cognitive effects throughout childhood, mental health and behavioral problems, and physical disabilities, the costs of which are likely to be borne by the citizens of Walker County for many years to come.

287. While opioid use proliferated, and its insidious and devastating effects were hoisted upon the citizens of Walker County and the Nation, the companies responsible for this scourge profited in a manner incomprehensible to even the most cynical members of society. One report estimated that 254 million opioid prescriptions were filled in 2010 alone, enough to medicate every adult in the U.S. for a month on a round-the-clock basis. In that same year, pharmaceutical companies generated revenues of $11 billion from opioid sales alone. The opioid market is now worth nearly $10 billion a year in sales in the United States, according to a 2016 report.

288. Internal documents establish that these Defendants realized that direct messaging and medical guidelines sponsored by them would be viewed more critically than messaging and ads by apparently independent third-party health care organizations (Front Groups). With this knowledge, the industry set about to manipulate the flow of information to the medical community and their patients. Specifically, The Federation of State Medical Boards ("FSMB'"), American Pain Society ("APS"), American Academy of Pain Medicine ("AAPM"), and The American Geriatrics Society ("ABS") are supposedly independent organizations concerned with patient wellbeing. However, these organizations were in fact funded by the Defendants for the sole purpose of having seemingly independent pain

organizations espousing the virtues of opioid use, and particularly of distributing false information regarding abuse and addiction.

289. A 2004 iteration of the FSMB Guidelines, as well as the 2007 book adopted from the 2004 guidelines, Responsible Opioid Prescribing, taught not that opioids could be appropriate in limited cases or after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option. Unbelievably, the regulations changed so that doctors could be censored or have other action taken against them for failure to use opioids as a treatment of first choice. These guidelines were posted online and were available to and intended to reach Walker County physicians. The publication of Responsible Opioid Prescribing was backed largely by drug manufacturers, including Defendants Cephalon, Endo, and Purdue. The FSMB financed the distribution of Responsible Opioid Prescribing through its member boards by contracting with drug companies, including Purdue, Endo and Cephalon, for bulk sales and distribution to sales representatives for distribution to prescribing doctors.

290. In all, 163,131 copies of Responsible Opioid Prescribing were distributed to state medical boards and through the boards, to practicing doctors, and the FSMB benefitted by earning approximately $250,000 in revenue and commissions from their sale. The FSMB website describes the book as the "leading continuing medication education (CME) for prescribers of opioid medications."

291. Locally, the Texas Pain Society had an active presence in Walker County and offered guidance to physicians and patients on the issue of pain management The "TexasPain.org" website, for example, assured patients about the use of opioids, stating: "Research shows that the chance of people with chronic pain becoming addicted to pain-

relieving drugs is extremely small. When taken properly for pain, drugs can relieve pain without addiction. Needing medication to control your pain is not addiction." The Texas Pain Society was in fact an organization supported by various members of the drug industry, including Defendants Purdue, Endo, and Cephalon.

292. Defendants' misconduct has also increased Plaintiff's cost of private health insurance in Walker County. Group participants may pay all or part of the premium directly, or their employers may pay all or part of the premium directly. Individual purchasers (or members of their family) pay the entire premium directly. The "deductible" in a health-insurance plan is the amount the insured must pay each period (usually annually) before insurance starts to cover healthcare costs. A "co-pay" is a flat amount the insured pays per claim, such as a doctor visit or prescription. "Coinsurance" is the percentage of a bill that the insured pays under some plans after the deductible is met. Deductibles and co-payments often are higher under individual plans.

293. As a direct and proximate result of the conduct described herein, natural and corporate persons have sustained losses and injuries in the form of higher premiums, deductibles, and co-payments/co-insurance. Health care insurers in Walker County have paid (and expect to continue to pay) substantial amounts for opioid prescriptions that would never have been prescribed and/or filled absent all Defendants' misconduct and have also paid (and expect to continue to pay) substantial amounts for treatment of individuals who became addicted to opioids and/or who became addicted to heroin or other drugs because of opioid use. Many of those individuals who became addicted to opioids—or who became addicted to heroin or other drugs because of opioid use—would never have become addicted or even received access to opioids absent Defendants' conduct described herein.

These insurers have also paid for numerous other costs proximately caused by all Defendants' conduct, including care for babies born addicted to opioids, emergency-room treatments, and other claims.

294. Plaintiff purchasers of private health insurance have been damaged as a result of paying prices that are higher as a direct result of all Defendants' misconduct. Walker County health insurers are easily able to—and do—pass higher costs onto their insureds. Premiums in health insurance markets do not reflect individual differences in costs, meaning that all insureds bear higher costs inflicted by the highest-risk insureds.

295. In Walker County, as in most other counties, insurers charge premiums based on assigned rate classes, a pool of insured individuals with similar health status. Because the premium charged is uniform for the entire risk class, excessive claims experienced by others raise premiums for everyone. This empirical reality makes economic sense. Insurers cannot know ex ante if an individual insured will take and become addicted to opioids, with the corresponding costs that ensue for that patient. So, insurers charge every insured a higher premium—including the majority of insureds who never take opioids—to pay for the risk of future, opioid-related claims.

296. This is partially because insured patients with opioid abuse or dependence diagnoses cost health insurers more than average patients, in Walker County and nationwide. In 2015, total annual per-patient charges (the costs of providing a health service) and allowed amounts (the maximum an insurer will pay for a covered health service) for services for patients with opioid abuse and dependence diagnoses were 550% higher than for the average insured patient. Similarly, professional charges and allowed amounts grew by over 1,000% for patients diagnosed with opioid abuse or dependence

from 2011 to 2015, further increasing insurance companies' incentive to increase their customers' rates.

297. Thus, as the opioid crisis has barreled forward across the country and in Walker County, so has the pressure on insurance companies to raise premiums. Indeed, by one estimate, private insurance claims related to opioid dependence rose by an astonishing 3,200% nationwide from 2007 to 2014, and upon information and belief by a comparable percentage in Walker County, with the brunt of this burden falling on those aged 19 to 35. This makes sense in light of the demonstrated increase in opioid-related emergency room visits and treatment center admissions, along with the growth in the percentage of privately insured Americans and residents of Walker County over this period.

Conclusion

298. The medical community and the public rely upon the integrity of prescription drug companies to advertise, promote, and market their products in conformity with both common law and statutory obligations. There is an overriding ability to promote these products in a manner that is truthful and that discloses important safety information. Similarly, when drug companies engage in indirect forms of communication, they have a concomitant obligation to disseminate only accurate and honest product information. This responsibility applies to the myriad vehicles by which drug makers influence product use: marketing brochures for physicians and patients, TV commercials, FAQ's, continuing medical education programs, web sites, and on and on. In all of these instances, the members of the opioid drug industry have both common law and regulatory restraints that govern their behavior. It is alleged that the corporate Defendants violated these rules and disseminated untrue, misleading, and erroneous information about opioids.

299. The joined Defendants, corporate and individual, are also guilty of acting in concert to profit from the opioid crisis. The drug manufacturers and distributors, as alleged herein, were responsible for maintaining an environment in which opioid drugs were available in massive quantities and were subject to significant rates of diversion to illicit uses. Plaintiff contends that the vast majority of healthcare providers who prescribed opioids, and clinics or pharmacies that dispensed them, were legitimate businesses. However, there are individuals who take advantage of the profligate system that the corporate Defendants supported and supplied. The named individual Defendants are guilty of exploiting the opioid drug distribution system for profit, at the expense of the citizens of Walker County. However, the individual Defendants would have been unable to perpetrate their tortious acts if the corporate Defendants had fulfilled their responsibilities under Texas law to monitor, detect, investigate, and report suspicious orders of prescription opiates.

300. As a result of Defendants' wrongful conduct, the number of prescriptions for opioids increased sharply, reaching over 250 million prescriptions in 2012, almost enough for every person in the United States to have a bottle of pills. This represents an increase of three hundred percent (300%) since 1999.

Causes of Action

A. PUBLIC NUISANCE

301. Plaintiff alleges a claim of Public Nuisance against all Defendants.

302. Defendants' acts and omissions, as described above, constitute a public nuisance in Walker County. Through their negligence and intentional acts, Defendants have unreasonably interfered with Walker County's right to public health, public safety, public peace, public comfort, and public convenience.

303. Defendants, individually and in concert with each other, have contributed to and/or assisted in creating and maintaining a condition that is harmful to the health and safety of Walker County residents and/or unreasonably interferes with the peace and comfortable enjoyment of life.

304. The public nuisance created by Defendants' actions is substantial and unreasonable. That nuisance has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit.

305. All Defendants' actions have increased the cost of insuring individuals, and all Walker County employees and residents who pay insurance premiums have been injured.

306. Plaintiff, Walker County, brings this claim of public nuisance seeking injunctive relief, abatement of the nuisance, and for damages suffered as a result of the nuisance. With regard to damages, Plaintiff affirmatively pleads that Defendants' acts and omissions constitute a continuing tort and damages are sought for all injuries caused by the continuing tort during the entire time period described above.

307. Plaintiff is seeking damages including, but not limited to, reimbursement for the substantial costs of dealing with all aspects of the opioid crisis such as health care, emergency response, social services, law enforcement and the lost revenue and opportunity resulting from the tragic loss of its community members to the opioid epidemic caused by Defendants.

B. NEGLIGENCE

308. Plaintiff alleges a claim of negligence against all Defendants.

309. Manufacturing Defendants have a duty to exercise reasonable care in marketing its opioids to physicians treating residents of Walker County and Walker County residents.

Manufacturing Defendants have breached their duty by knowingly and fraudulently misrepresenting the benefits of, and downplaying the risks of, opioids for chronic pain.

310. Manufacturing Defendants have used deceitful marketing and other schemes to increase profits at the cost of public health causing an opioid epidemic. Manufacturing Defendants have acted willfully, wantonly, and maliciously.

311. Likewise, Distributor Defendants have a duty to exercise ordinary care in distributing opioids. Distributor Defendants have breached their duty by failing to prevent or reduce the distribution of opioids, or to report the increase in the distribution and/or sale of opioids.

312. Distributor Defendants have intentionally failed to prevent or reduce the distribution of opioids, or to report any increases in the sale of opioids, so that they could increase profits and receive rebates or kick-backs from Manufacturing Defendants. Distributor Defendants have acted willfully, wantonly, and maliciously.

313. As a proximate result, Manufacturing and Distributor Defendants and its agents have caused Walker County to incur excessive costs to treat the opioid epidemic in its county, including but not limited to increased costs of social services, health systems, law enforcement, judicial system, and treatment facilities. The Manufacturer Defendants knew and should have known that misleading doctors and insurers about the safety and efficacy of opioids for long-term pain treatment would cause significant costs, not just to those for whom opioids were an ineffective and dangerous treatment, but to insurers that absorb healthcare costs, and thus ultimately to insurance customers. Similarly, the Distributor Defendants knew and should have known that allowing diversion of opioids would cause significant costs to consumers, insurers, and insurance customers.

314. All Defendants failed to implement policies and procedures to document the flow of opioids through the distribution network. All Defendants failed to properly train or require employees and affiliates to identify, report and investigate any improprieties in the flow of opioids. As a proximate result, all Defendants have caused Walker County to incur excessive costs to treat the opioid epidemic in its county, including but not limited to increased costs of social services, health systems, law enforcement, judicial system, and treatment facilities.

315. All Defendants undertook to perform services related to the provision of opioid pharmaceuticals to Walker County. All Defendants failed to exercise reasonable care in performing those services, thereby causing Walker County to incur excessive costs to treat the opioid epidemic in its county, including but not limited to increased costs of social services, health systems, law enforcement, judicial system, and treatment facilities.

316. Plaintiff, Walker County, is therefore entitled to actual and punitive damages. With regard to damages, Plaintiff affirmatively pleads that Defendants' acts and omissions constitute a continuing tort and damages are sought for all injuries caused by the continuing tort during the entire time period described above.

C. GROSS NEGLIGENCE

317. Plaintiff brings a claim of Gross Negligence against all Defendants.

318. Defendants' hiring of KOLs, Front Groups, and others to spread its fraudulent message that opioids were useful and beneficial for chronic pain was grossly negligent and done with conscious indifference or reckless disregard for the safety of others.

319. Each Defendant's actions and omissions as described herein, singularly or in combination with each other, was malicious resulting in damages and injuries to Walker County and its residents.

320. At every stage, Defendants knew or should have known that their conduct would create an unreasonable risk of physical harm to others, including Walker County and its residents, and should be held liable in punitive and exemplary damages to Walker County.

D. TEXAS CONTROLLED SUBSTANCES ACT ("TCSA")

321. Plaintiff brings a claim for violation of TCSA against the Distributor Defendants.

322. Distributor Defendants have knowingly distributed, delivered, administered, or dispensed a controlled substance in violation of the Texas Controlled Substances Act §481.128(a)(1) by deceiving practitioners into prescribing, dispensing, delivering, or administering a controlled substance, or causing a controlled substance to be administered when there is no valid medical purpose. Tex. Health & Safety Code §481.071.

323. As alleged herein, each Distributor Defendant, at all times relevant to this Complaint, violated the Texas Controlled Substance Act by making deceptive representations about using opioids to treat chronic pain. Each Distributor Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Distributor Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

324. Distributor Defendants' deceptive representations and concealments were reasonably calculated to deceive practitioners treating Walker County residents into prescribing opioids without any valid medical purpose, and Distributor Defendants continue to do so to this day.

325. Distributor Defendants' prescribed opioids without a valid medical purpose in violation of Texas Health & Safety Code Section 481.071(a).

326. As a direct and proximate cause of Distributor Defendants' and the physicians' deceptive conduct, Walker County should be awarded civil penalties pursuant to the Texas Controlled Substances Act.

E. PRAYER FOR RELIEF

327. WHEREFORE, Plaintiff respectfully prays:

a. That the acts alleged herein be adjudged and decreed to be unlawful and that the Court enter a judgment declaring them to be so;

b. That Defendants be enjoined from, directly or indirectly through KOLs, Front Groups or other third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, and from continuing to violate Texas law;

c. That Plaintiff recover all measures of damages, including punitive and exemplary damages, allowable under the law, and that judgment be entered against Defendants in favor of Plaintiff;

d. That Plaintiff recover restitution on behalf of Walker County consumers who paid for opioids for chronic pain;

e. That Plaintiff recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorneys' fees as provided by law; and

f. That Defendants be ordered to abate the public nuisance that they created in in violation of Texas common law.

Date: January 11, 2019

Respectfully Submitted,

Correro & Leisure, P.C.

Correro & Leisure, P.C.

By: 

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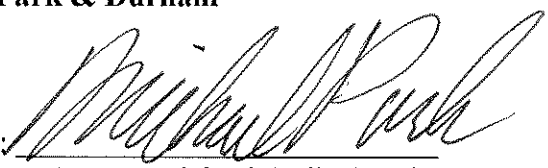
By: 

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PLAINTIFF HEREBY DEMANDS TRIAL BY JURY

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MDL PRETRIAL CAUSE NO. 2019-29777

COUNTY OF WALKER, Plaintiff,	§	IN THE DISTRICT COURT
v.	§	OF WALKER COUNTY, TEXAS
ABBOTT LABORATORIES, ET AL., Defendants.	§	12th JUDICIAL DISTRICT

****

MASTER FILE NO. 2018-63587

IN RE: TEXAS OPIOID LITIGATION	§	IN THE DISTRICT COURT 152ND JUDICIAL DISTRICT HARRIS COUNTY, TEXAS

MISSION PHARMACAL COMPANY'S ORIGINAL ANSWER

TO THE HONORABLE JUDGE OF SAID COURT:

MISSION PHARMACAL COMPANY ("Mission Pharmacal"), Defendant, files this its Original Answer as follows:

I.

MISSION PHARMACAL generally denies the allegations claimed in Plaintiff's Original Petition and demands strict proof by a preponderance of the evidence of all Plaintiff's allegations pursuant to TEX. R. CIV. PRO. 92.

II.

PRAYER

WHEREFORE, PREMISES CONSIDERED, MISSION PHARMACAL COMPANY, prays that Plaintiff take nothing by reason of it action; that Defendant recover its costs; and that it be granted any and all other relief to which it may be entitled.

Respectfully submitted,

DYKEMA GOSSETT, PLLC
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ATTORNEYS FOR DEFENDANT,
MISSION PHARMACAL COMPANY

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing document was served on all counsel of record via the Court's electronic filing system on May 1, 2019:

/s/ Jane E. Bockus
Jane E. Bockus

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

Certified Document Number: 85051435 Total Pages: 3

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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MDL PRETRIAL CAUSE NO. 2019-29777

COUNTY OF WALKER, Plaintiff,	§	IN THE DISTRICT COURT
v.	§	OF WALKER COUNTY, TEXAS
ABBOTT LABORATORIES, ET AL., Defendants.	§	12th JUDICIAL DISTRICT

****

MASTER FILE NO. 2018-63587

IN RE: TEXAS OPIOID LITIGATION	§	IN THE DISTRICT COURT 152ND JUDICIAL DISTRICT HARRIS COUNTY, TEXAS

NEXGEN PHARMA, INC.'S ORIGINAL ANSWER

TO THE HONORABLE JUDGE OF SAID COURT:

NEXGEN PHARMA, INC., Defendant, files this its Original Answer as follows:

I.

NEXGEN PHARMA, INC. generally denies the allegations claimed in Plaintiff's Original Petition and demands strict proof by a preponderance of the evidence of all Plaintiff's allegations pursuant to TEX. R. CIV. PRO. 92.

II.

PRAYER

WHEREFORE, PREMISES CONSIDERED, NEXGEN PHARMA, INC., prays that Plaintiff take nothing by reason of it action; that Defendant recover its costs; and that it be granted any and all other relief to which it may be entitled.

Respectfully submitted,

DYKEMA GOSSETT, PLLC
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ATTORNEYS FOR DEFENDANT,
NEXGEN PHARMA, INC.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing document was served on all counsel of record via the Court's electronic filing system on May 1, 2019:

/s/ Jane E. Bockus
Jane E. Bockus

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

Certified Document Number: 85051455 Total Pages: 3

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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TRIAL CAUSE NO. 1929076

COUNTY OF WALKER	§	**IN THE DISTRICT COURT**
	§	
	§	
Plaintiff,	§	
vs.	§	**12TH JUDICIAL DISTRICT**
	§	
PURDUE PHARMA L.P., *et al.*	§	
	§	
	§	
Defendants.	§	**WALKER COUNTY, TEXAS**

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MDL PRETRIAL CAUSE NO. 2019-29777
(MDL MASTER CAUSE NO. 2018-63587)

	§	**IN THE DISTRICT COURT**
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	§	
IN RE TEXAS OPIOID LITIGATION	§	**152ND JUDICIAL DISTRICT**
	§	
	§	
	§	
	§	**HARRIS COUNTY, TEXAS**
	§	

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DEFENDANTS INSYS THERAPEUTICS, INC. AND INSYS MANUFACTURING, LLC'S ORIGINAL ANSWER TO PLAINTIFF'S ORIGINAL PETITION

Defendants INSYS Therapeutics, Inc. and INSYS Manufacturing, LLC (together, "Insys") file this Original Answer ("Answer") to Plaintiff the County of Walker's ("Plaintiff") Original Petition ("Petition") and respectfully show the following:

I. General Denial

Under Rule 92 of the Texas Rules of Civil Procedure, Insys generally denies all of the allegations contained in the Petition, including any and all amendments and supplements, and

demands strict proof thereof and that Plaintiff prove its allegations under the burdens of proof required by the laws of the State of Texas.

II. Affirmative and Other Defenses

Under Rule 94 of the Texas Rules of Civil Procedure, and without waiving its General Denial, Insys asserts the following affirmative defenses responsive to the Petition and any and all amendments and supplements, which are asserted both as affirmative defenses and as alternative defenses. Insys only undertakes the burden of proof as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated in this Answer. Nothing stated in this Answer constitutes an acknowledgment or concession that Insys bears any burden of proof on any issue on which it would not otherwise bear a burden. Insys reserves the right to freely amend its Answer.

1. Failure to State a Claim. Plaintiff fails to state a claim upon which relief can be granted. Among other deficiencies:

- Insys has no legal relationship with Plaintiff from which any duty could arise and Plaintiff fails to plead any duty Insys owed or owes to Plaintiff.
- Plaintiff fails to plead alleged conduct by Insys with adequate specificity. Plaintiff does not adequately distinguish among Defendants, their drugs, their drugs' labels, their promotional techniques, or the relevant time periods, and fails to specify what Insys is alleged to have done, when, where, and/or to whom.
- Plaintiff fails to plead and cannot establish that it incurred any costs for Insys' only opioid product, SUBSYS®, that was inappropriate or not medically unnecessary, or that Insys's allegedly improper conduct caused any health care provider to write any unnecessary, ineffective or harmful opioid prescriptions.
- Plaintiff fails to adequately allege a causal connection between Insys' alleged misconduct and Plaintiff's alleged injury.

- Plaintiff fails to plead a legally cognizable injury. Though Plaintiff claims that it has been damaged by the Defendants' acts, it fails to plead any connection of any conduct by Insys to any alleged damages.

- Plaintiff has failed to allege any particularized injury or special damages. All claims for special damages are barred under Rule 56 of the Texas Rules of Civil Procedure for failure to specifically state any items of special damages that are claimed.

- Plaintiff fails to plead any actionable misrepresentation, omission, or any conduct at all made by or attributable to Insys.

2. Failure to Plead Fraud. To the extent that Plaintiff alleges fraud, fraudulent concealment, or similar conduct, Plaintiff has failed to plead fraud with sufficient particularity. Among other things, Plaintiff acknowledges that Insys manufactures and sells the product SUBSYS®, which is regulated by the Food and Drug Administration ("FDA"). The FDA-approved product label for SUBSYS® has, at all relevant times, fully disclosed the risks of abuse, misuse, addiction, which can lead to overdose or death, and of the potential adverse effects (including dependence, tolerance, addiction, and death), the indications and dosing for SUBSYS®, among other things. In addition, SUBSYS® has at all times been subject to the FDA-mandated Transmucosal Immediate Release Fentanyl ("TIRF") Risk Evaluation Mitigation Strategy ("REMS") program, which ensures that anyone who will prescribe, dispense or receive SUBSYS® outside of a hospital setting fully understands the risks of prescribing and using SUBSYS®.

3. Lack of Reliance. Plaintiff's claims may be barred, in whole or in part, because neither the medication users nor their prescribers relied to their detriment upon any statement by Insys in determining to prescribe or use the medications at issue. Among other things, Plaintiff acknowledges that Insys manufactures and sells the product SUBSYS®, which is regulated by the FDA. The FDA-approved product label for SUBSYS® has, at all relevant times, fully disclosed

the risks of abuse, misuse, and addiction, which can lead to overdose or death, and of the potential adverse effects (including dependence, tolerance, addiction, and death), the indications and dosing for SUBSYS®, among other things. In addition, SUBSYS® has at all times been subject to the FDA-approved TIRF REMS program, which ensures that anyone who will prescribe, dispense or receive SUBSYS® outside of a hospital setting fully understands the risks of prescribing and using SUBSYS®.

4. TIRF-REMS. The claims asserted in the Petition regarding SUBSYS® are barred, in whole or in part, by the FDA-approved TIRF REMS Program, including, but not limited to, the requirements imposed on prescribers of TIRF medicines and patients.

5. Speculative and Remote Injuries. The alleged injury asserted by Plaintiff is too remote from the alleged conduct of Insys to be a basis for liability as a matter of law and due process. For example, Insys did not even begin selling SUBSYS® until March 2012, could not have caused the alleged opioid epidemic that pre-existed its launch of SUBSYS® or played any part in the alleged "misrepresentations" or "scheme" that Plaintiff alleges caused an opioid epidemic.

6. Failure to Identify Medically Unnecessary or Improper Prescriptions. Plaintiff's claims are barred and should be dismissed because Plaintiff has not identified the allegedly inappropriate, unnecessary, or otherwise improper SUBSYS® prescriptions that it contends are at issue and on which it bases its claims. To the extent SUBSYS® was prescribed at all in the Plaintiff's jurisdiction, SUBSYS® prescriptions constituted a non-material percentage of the opioids sold in the jurisdiction.

7. Intervening and Superseding Causes. To date, Plaintiff has failed to identify any

injury or damages caused by Insys and has failed to identify a single prescription of SUBSYS® Plaintiff paid for or that was medically unnecessary or improper. However, if Plaintiff has sustained any injuries or damages, such were the result of intervening or superseding events, factors, occurrences, or conditions, which were not reasonably foreseeable and in no way caused by Insys and for which Insys is not liable. The following non-exhaustive list of alternative causes may, in whole or in part, address Plaintiff's claim of causation and proximate causation, render the damages too remote as a matter of law, and/or interrupt or break the chain of causation that Plaintiff must prove between Insys' alleged conduct and the purported harms described in the Petition:

- Plaintiff's failure to exercise due care or properly discharge its duties or exercise its discretion in the assessment and decision of whether to authorize or approve the payment of claims for medications or medical services.
- Criminal drug trafficking and other means of criminal diversion of prescription drugs from legitimate channels of distribution and dispensation, and/or re-sale or re-distribution via illegal channels to and/or use by individuals without lawful prescriptions.
- An individual's failure to follow a physician's or other prescriber's directions for use of prescription opioid medications.
- Illicit use or abuse of SUBSYS® on the part of medication users.
- Alteration, modification, misuse, or abuse on the part of medication users of SUBSYS®.
- Wrongful or negligent conduct by physicians or other prescribers, including, for example, submission of fraudulent prescriptions, writing prescriptions for patients who do not have a medically proper use for them, failure to attend to the risk of abuse and addiction, and operation of a "pill mill."
- Wrongful or negligent conduct by a pharmacy, including, for example, dispensing of prescription medications without a proper prescription or failure to report indications of diversion, abuse, or addiction.

- Use, misuse, or abuse of illegal drugs or medications other than SUBSYS® on the part of medication users.

8. Preexisting Conditions and Idiosyncratic Reactions. Plaintiff's injuries and damages, if any, are barred to the extent they were due to preexisting conditions, idiosyncratic reaction to the medications on the part of the medication users, and/or occurred by operation of nature or as a result of circumstances over which Insys had, and continues to have, no control.

9. Learned Intermediary Doctrine. Plaintiff's claims are barred by the learned intermediary doctrine. At all relevant times, the physicians and other health care providers that prescribed an opioid medication that was filled with an Insys product were in the position of learned intermediaries, who used their independent medical judgment in making their prescribing and treatment decisions for a given patient. Those prescribers had many sources of information about Insys' medications available to them, including the FDA-approved product labeling for the Reference Listed Drug for Insys' product that informed prescribers of the risks and benefits of the medication, and those prescribers relied on a variety of factors separate from and unrelated to Insys' alleged misrepresentations in making their prescribing decisions.

10. Sophisticated User Doctrine. Plaintiff's claims are barred by the sophisticated user doctrine. Because of their training and experience, physicians and other health care providers who prescribe opioids know or reasonably should know of the potential risks, and Insys had no duty to warn and cannot be held liable for failing to warn of risks and complications of which members of the relevant medical community knew or should have known.

11. Informed Consent. The physicians and other health care providers who prescribe FDA-approved opioid medications have a duty to provide patients with material information so

they can make informed decisions about a proposed treatment, and Insys is entitled to rely on this duty—as well as the prescribers' professional education, training and experience with respect to potential risks and complications associated with opioid medications. Because prescribers were provided with adequate warnings, Insys is entitled to rely on prescribers' provision of information to patients and Plaintiff's claims are barred by patients' provision of informed consent.

12. No Liability for Third Party Conduct. Plaintiff's claims against Insys, and Plaintiff's damages, are barred to the extent that any rely on or implicate the negligent, intentional, malicious, criminal, and/or otherwise unlawful acts or omissions of third parties not subject to Insys' control or authority and for which Insys is not responsible and cannot be held liable. These include, but are not limited to, health care providers, prescribers, patients, and other third parties whom Plaintiff alleges disseminated fraudulent, deceptive, or misleading statements and marketing materials regarding opioid products and/or engaged in the unauthorized or illicit prescription, dispensing, diversion, or use of prescription opioid products. Insys' liability, if any, therefore must be reduced or negated to the extent that third parties have contributed to, or caused, Plaintiff's injuries.

13. Failure to Mitigate. Plaintiff's claims are barred, in whole or in part, by Plaintiff's failure to mitigate any damages allegedly sustained.

14. Contributory or Comparative Fault. Plaintiff's claims are barred and/or reduced by contributory or comparative negligence and contributory or comparative fault, and Insys invokes the contribution provisions of Chapter 32 of the Texas Civil Practice and Remedies Code and the proportionate responsibility and contribution provisions of Chapter 33 of the Texas Civil Practice and Remedies Code.

15. Caps on Recovery. Plaintiff's claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

16. Statute of Limitations and/or Repose. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and of repose.

17. Laches, Waiver, Unclean Hands, Estoppel. Plaintiff's claims are barred, in whole or in part, by doctrines of laches, waiver, unclean hands, and/or estoppel.

18. First Amendment and Related Rights and Protections. To the extent that Plaintiff's claims relate to Insys's advertising, public statements, membership or participation in advocacy or other organizations, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by Article I, § 8 of the Constitution of the State of Texas or that of any other state whose laws may apply, such claims are barred.

19. Failure of Exemplary Damages. To the extent that Plaintiff seeks or will seek punitive or exemplary damages or other civil penalties, such are barred or reduced under: (a) the following provisions of the United States Constitution: the Commerce Clause of Article I, § 8; the Contracts Clause of Article I, § 10; the prohibition against *ex post facto* laws embodied in Article I, § 10; the Supremacy Clause of Article VI; the Free Speech Clause of the First Amendment; the Due Process Clauses of the Fifth and Fourteenth Amendments; the Takings Clause of the Fifth Amendment; the Excessive Fines Clause of the Eighth Amendment; the Right to Trial by Jury of the Seventh Amendment; the Equal Protection Clause of the Fourteenth Amendment; (b) similar or corresponding provisions of the Texas Constitution and any other applicable rule, case, statute, or constitutional provision related to the request for punitive or exemplary damages or other civil

penalties; and (c) Chapter 41 of the Texas Civil Practice and Remedies Code, the protections and requirements of which Insys specifically invokes. Any law, statute or other authority purporting to permit the recovery of punitive damages or civil penalties in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages or civil penalties and/or the amount, if any; (2) is void for vagueness in that it fails to provide adequate advance notice as to what conduct will result in punitive damages or civil penalties; (3) unconstitutionally may permit recovery of punitive damages or civil penalties based on harms to third parties, out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) unconstitutionally may permit recovery of punitive damages or civil penalties in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to Insys; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any award of punitive damages or civil penalties; (7) lacks constitutionally sufficient standards for appellate review of any award of punitive damages or civil penalties; (8) would unconstitutionally impose a penalty, criminal in nature, without according to Insys the same procedural protections that are accorded to criminal defendants under the constitutions of the United States, this State, and any other state whose laws may apply; and (9) otherwise fails to satisfy U.S. Supreme Court precedent, including, without limitation, *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991); *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of N. Am. v. Gore*, 517 U.S. 559 (1996); *State*

Farm Ins. Co. v. Campbell, 538 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and similar Texas cases, and their progeny.

20. No Conduct Sufficient for Punitive Damages. No act or omission of Insys was malicious, willful, wanton, or was undertaken under circumstances in which reckless disregard may be inferred. No act or omission of Insys was pursued intentionally for the purpose of causing injury or damage, and, consequently, any award of exemplary or punitive damages is barred.

21. Pre-Market Approval. To the extent that Plaintiff seeks punitive, exemplary, or aggravated damages, any such damages are barred because the product at issue, and its warnings and labeling, were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301 and/or otherwise meet the presumption requirement in Section 82.007 of the Texas Civil Practice and Remedies Code.

22. Improper Financial Arrangement. Insys' rights under the Due Process Clause of the U.S. Constitution and applicable state Constitution or statute are violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding. To the extent a contingency fee agreement gives Plaintiff's counsel a financial interest in the outcome of this proceeding, it violates Insys' due process rights.

23. Lawful Activity. Insys's liability, if any, will not result from its conduct but is solely the result of an obligation imposed by law, and thus Insys is entitled to complete indemnity, express or implied, by other parties.

24. Several Liability and Allocation. Any defendant's liability must be limited in accordance with the percentage of fault allocated to it by the ultimate trier of fact and/or law. Each

defendant may only be severally liable for any injuries or expenses. Plaintiff's alleged damages are not indivisible but comprise separate and discrete costs.

25. Set-Off. Should Insys be held liable to Plaintiff, which liability is specifically denied, Insys would be entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasor(s) for the same injuries alleged in the Petition, as provided under Chapter 33 of the Texas Civil Practice and Remedies Code and/or any other rule, statute, or regulation.

26. Primary Jurisdiction. The claims asserted in the Petition are barred, in whole or in part, because federal agencies have exclusive or primary jurisdiction over the matters asserted in the Petition.

27. Preemption. Plaintiff's claims are barred because they are preempted by federal law and regulation, including by the U.S. Food, Drug, and Cosmetic Act ("FDCA"), the regulations promulgated pursuant thereto, and the Supremacy Clause of the United States Constitution. *See, e.g.*, 21 U.S.C. § 301 *et seq.*; 21 C.F.R. § 201.1 *et seq.*, 202.1 *et seq.*, 203.1 *et seq.*; Tex. Health & Safety Code Ann. § 431.001 *et seq.*

28. *Buckman.* Plaintiff's claims are barred, in whole or in part, by *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001).

29. Agency Deference. Plaintiff's claims are barred, in whole or in part, by the deference that common law gives to discretionary actions by the FDA under the FDCA and regulations promulgated under the FDCA.

30. State of the Art. Plaintiff may not recover from Insys because the methods, standards, or techniques of designing, manufacturing, labeling and distributing of the prescription medications at issue complied with and were in conformity with the generally recognized state of

the art at the time the product was designed, manufactured, labeled, and distributed.

31. Statements Not Misleading. Statements in Insys' marketing materials comporting with FDA-approved uses are not misleading as a matter of law or otherwise actionable.

32. Due Process and Ex Post Facto. Plaintiff's claims are barred because they violate procedural and substantive due process rights under the Fourteenth Amendment to the U.S. Constitution and similar provisions of the Texas Constitution, and the right to be free from retroactive or ex post facto laws as guaranteed by Article I, § 10 of the United States Constitution and similar provisions of the Texas Constitution.

33. Commerce Clause. Plaintiff's claims are barred, in whole or in part, by the Commerce Clause of the United States Constitution.

34. Failure to Join Indispensable Parties. Plaintiff has failed to join one or more necessary and indispensable parties, including without limitation health care providers, prescribers, patients, and other third parties whom Plaintiff alleges engaged in the unauthorized or illicit prescription, dispensing, diversion, or use of prescription opioid products.

35. Economic Loss Rule. Plaintiff's claims against Insys are barred or limited by the economic loss rule.

36. Res Judicata and Collateral Estoppel. Plaintiff's claims against Insys are barred by the doctrines of res judicata and collateral estoppel.

37. Adequate Remedy at Law. To the extent Plaintiff attempts to seek equitable relief, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

38. Duplicative or Double Recovery. Plaintiff's claims are barred, in whole or in part, to the extent it seeks to recover any damages, restitution, costs, or other payments that have been

reimbursed, paid or borne by other persons or entities. Any verdict of judgment that might be recovered must be reduced by those amounts that have already been or will in the future, with reasonable certainty, be paid to Plaintiff by others.

39. No Benefit from Plaintiff. Plaintiff's claim for unjust enrichment is barred or limited because Insys did not receive and retain any alleged benefit from Plaintiff.

40. Standing. Plaintiff's claims are barred or limited for lack of standing. Plaintiff has no *parens patriae* or other authority to bring the claims alleged, and Plaintiff fails to plead any basis for standing.

41. Subrogation. Plaintiff has failed to comply with the requirement that it identify each patient in whose claim(s) it has a subrogation interest.

42. Assumption of Risks. Any recovery against Insys is barred or limited under the principle of assumption of the risk.

43. Known Risks. Plaintiff's claims are barred, in whole or in part, to the extent they are based on alleged harms resulting from known risks or dangers associated with opioid products that are unavoidable even within the scope of prescribed and intended use, but that are reasonable in comparison to the benefits conferred.

44. Constraints on Police Powers. Plaintiff's claims and damages are barred or limited, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers by a state county or municipality.

45. No Proximate Cause. Plaintiff's damages, if any, were not proximately caused by any act or omission attributable to Insys.

46. Separation of Powers. Plaintiff's claims are barred or limited by the separation of

powers doctrine.

47. No Public Right. Plaintiff's claim of public nuisance is barred or limited because no action of Insys involved interference with real property, illegal conduct perpetrated by third-parties involving the use of an otherwise legal product does not involve a public right against the manufacturer sufficient to state a claim for public nuisance, the alleged public nuisance would have impermissible extraterritorial reach, and the alleged conduct of Insys is too remote from the alleged injury as a matter of law and due process. Plaintiff's claim of public nuisance is further barred because nuisance is not a separate cause of action.

48. Improper Joinder. Plaintiff's claims against Insys and other defendants do not arise out of the same transaction, occurrence, or series of transactions or occurrences as required by the rules for joinder of parties. Plaintiff fails to connect any of the alleged marketing activities of Insys to those of other defendants. Accordingly, the Court should dismiss Plaintiff's claims against Insys.

49. Ratification and Voluntary Payment Doctrine. Plaintiff's alleged losses, damages, injuries, harms, expenses, diminutions, or deprivations, if any, were caused in whole or in part by Plaintiff's ratification of Defendants' alleged conduct, including under the voluntary payment doctrine. Such ratification would include, for example, Plaintiff's continued allowance of opioid prescriptions after it had concluded such prescriptions were ineffective or harmful to their patients, constituents, members, beneficiaries, and/or consumers, medically unnecessary, or otherwise improper.

50. Limits on Relief Available. Plaintiff is not entitled to a declaratory judgment, injunction, or attorney's fees/legal expenses for these alleged claims.

51. Municipal Cost Recovery Rule. Plaintiff cannot recover the costs of provision of governmental services as damages.

52. Supremacy Clause. The Plaintiff's claims violate the Supremacy Clause of the United States Constitution.

53. Failure of Restitution or Rescission. Plaintiff is not entitled to any relief in the form of restitution or rescission because it cannot restore the *status quo ante*.

54. Controlling Law. Insys is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute of this State or any other state whose substantive law might control the action.

55. Chapter 82. All claims against Insys are barred under Chapter 82 of the Texas Civil Practice and Remedies Code, including, but not limited to, § 82.007(a).

56. Condition Precedent. All claims against Insys are barred due to the failure of the occurrence of a condition precedent.

57. Medical Damages Paid or Incurred. If Insys is found liable for medical damages, then those damages must be limited to the amount actually paid or incurred in accordance with Tex. Civ. Prac. & Rem. Code § 41.0105.

58. Loss of Earnings. If Insys is found liable for loss of earnings, then those damages must be limited in accordance with Tex. Civ. Prac. & Rem. Code § 18.091.

59. Prejudgment Interest. If Insys is found liable for pecuniary damages, then any prejudgment interest awarded should be reduced by reason of settlement offers outstanding, if any, during the prejudgment period in accordance with Title 4 of the Texas Finance Code. Further, if any exemplary damages are awarded against Insys, then Plaintiff is not entitled

to prejudgment interest on exemplary damages pursuant to Chapter 41 of the Texas Civil Practice and Remedies Code.

60. Incorporation of Other Affirmative Defenses. Insys incorporates by reference any affirmative defense alleged by another defendant in response to the Petition.

61. Reservation of Rights. Insys intends to add and rely upon such other and further defenses as may become apparent or available during the discovery in this action, and reserves the right to amend this list of defenses and/or its Answer to the Petition and/or to assert any such defenses in the future.

III. Prayer

Defendants INSYS Therapeutics, Inc. and INSYS Manufacturing, LLC pray that the Court dismiss the claims against them with prejudice, enter a final take-nothing judgment in their favor, award them attorneys' fees and costs, and grant such other relief, legal or equitable, to which they are entitled.

Dated: May 2, 2019

Respectfully submitted,

/s/ Nicholas A. Sarokhanian

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Counsel for INSYS Therapeutics, Inc. and INSYS Manufacturing, LLC

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing instrument was forwarded to all counsel of record via the Court's electronic filing system on May 2, 2019.

/s/ Nicholas A. Sarokhanian
Nicholas A. Sarokhanian

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

Certified Document Number: 85071310 Total Pages: 17

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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MDL PRETRIAL CAUSE NO. 2019-29777
TRIAL CAUSE NO. 1929076

COUNTY OF WALKER,	§	**IN THE DISTRICT COURT**
	§	
Plaintiff,	§	
	§	
v.	§	**12TH JUDICIAL DISTRICT**
	§	
ABBOTT LABORATORIES., *et al.*,	§	
	§	
Defendants.	§	**WALKER COUNTY, TEXAS**
	§	

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MDL MASTER FILE 2018-63587

	§	**IN THE DISTRICT COURT**
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	§	
	§	
IN RE TEXAS OPIOID LITIGATION	§	**152ND JUDICIAL DISTRICT**
	§	
	§	
	§	
	§	**HARRIS COUNTY, TEXAS**

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NEOS THERAPEUTICS, INC.'S ORIGINAL ANSWER

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, Defendant Neos Therapeutics, Inc. ("Defendant") and files its Original Answer and asserts as follows:

GENERAL DENIAL

Pursuant to Rule 92 of the Texas Rules of Civil Procedure, Defendant asserts a general denial, denies each and every allegation made by Plaintiff County of Walker, and demands strict proof thereof.

PRAYER

WHEREFORE, PREMISES CONSIDERED, Defendant prays that Plaintiff recovers nothing against Defendant Neos Therapeutics, Inc., and that the Original Petition be dismissed, that costs of court be assessed against Plaintiff, and for such other and further relief, both general and specific, at law or in equity, to which Defendant is justly entitled.

Respectfully submitted,

/s/ C. Scott Jones
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ATTORNEYS FOR DEFENDANT NEOS THERAPEUTICS, INC.

CERTIFICATE OF SERVICE

The undersigned hereby certified that a true and correct copy of the foregoing document was served upon all counsel of record via eFile Texas on this 3rd day of May 2019.

/s/ C. Scott Jones

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

Certified Document Number: 85083048 Total Pages: 2

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

In accordance with Texas Government Code 406.013 electronically transmitted authenticated documents are valid. If there is a question regarding the validity of this document and or seal please e-mail support@hcdistrictclerk.com

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By: Kimberly Garza
Filed: 5/3/2019 10:31 AM

MDL PRETRIAL CAUSE NO. 2019-29777

COUNTY OF WALKER, *Plaintiff*,	§	IN THE DISTRICT COURT
v.	§	12TH JUDICIAL DISTRICT
ABBOTT LABORATORIES et al., *Defendants.*	§	WALKER COUNTY, TEXAS

****

MASTER FILE NO. 2018-63587

	§	IN THE DISTRICT COURT
IN RE: TEXAS OPIOID LITIGATION	§	152ND JUDICIAL DISTRICT
	§	HARRIS COUNTY, TEXAS

DEFENDANTS JANSSEN PHARMACEUTICALS, INC. AND JOHNSON & JOHNSON'S ANSWER TO PLAINTIFF'S ORIGINAL PETITION

Janssen Pharmaceuticals, Inc., its predecessor company Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc. (collectively "Janssen"), and its parent company Johnson & Johnson ("J&J") hereby file their Original Answer to Plaintiff's Original Petition ("Petition").

General Denial

1. Pursuant to Rule 92 of the Texas Rules of Civil Procedure, J&J and Janssen generally deny—each and every, all and singular—the allegations set forth in Plaintiff's Petition and demand strict proof thereof.

Specific Denial

2. Pursuant to Rule 54 of the Texas Rules of Civil Procedure, J&J and Janssen specifically deny that Plaintiff has properly pled that all conditions precedent to Plaintiff's claims

have been performed or have occurred, and deny that such conditions precedent have been met in their entirety.

Affirmative and Other Defenses

3. Plaintiff's Petition fails to state a claim upon which relief may be granted, fails to state facts sufficient to constitute a cause of action, and fails to plead a legally cognizable injury.

4. Plaintiff's claims are barred in whole or in part for lack of standing.

5. Plaintiff's claims are barred in whole or in part because Plaintiff has no *parens patriae* or other authority to bring the claims alleged.

6. Plaintiff's claims are barred in whole or in part by the learned intermediary doctrine.

7. Plaintiff's claims are barred in whole or in part by the doctrine of laches.

8. Plaintiff's claims are barred in whole or in part by applicable limitations periods and/or statutes of repose.

9. Plaintiff's claims are barred in whole or in part by Plaintiff's failure to mitigate its alleged damages. The damages, if any, recoverable by Plaintiff must be reduced by the amount of damages caused by Plaintiff's failure to mitigate such damages.

10. Plaintiff's claims are barred in whole or in part by the economic loss rule.

11. Plaintiff's claims are barred in whole or in part by the municipal cost recovery rule.

12. Plaintiff's alleged damages and other requested forms of relief are too speculative and remote to serve as a legal basis for any recovery.

13. Plaintiff's claims are barred in whole or in part by the free public services doctrine insofar as Plaintiff seeks to recover, inter alia, the cost of opioids disbursed or paid for by Plaintiff.

14. Plaintiff's claims are barred in whole or in part because the injuries alleged resulted from one or more criminal acts by third parties.

15. Plaintiff's claims are barred in whole or in part because Plaintiff fails to plead any duty owed to Plaintiff by J&J and/or Janssen.

16. If Plaintiff has sustained any injuries or damages, such were the result of intervening or superseding events, factors, occurrences, or conditions, which were not reasonably foreseeable and in no way caused by J&J or Janssen and for which J&J and Janssen are not liable.

17. Plaintiff was negligent, careless, and/or at fault and contributed substantially to any alleged risks, injuries, and damages. Such negligence, carelessness, and fault bar, in whole or in part, the damages Plaintiff seeks in this case. Plaintiff also failed to exercise ordinary care, caution, or prudence to avoid its alleged injuries or damages; thus, Plaintiff's alleged injuries or damages were caused by its own acts or omissions. For all of these reasons, any damages awarded to Plaintiff should be barred or limited under the contribution and proportionate-responsibility provisions in Chapter 33 of the Texas Civil Practice and Remedies Code.

18. To the extent Plaintiff sustained any injuries or incurred any expenses as alleged in the Complaint, responsibility for 51% or more of those injuries or expenses lie with Plaintiff and/or parties or entities other than J&J or Janssen over whom J&J and Janssen have no supervision or control and for whose actions and omissions J&J and Janssen have no

responsibility. As such, at most, J&J and Janssen may only be severally liable for Plaintiff's injuries or expenses.

19. Any damages Plaintiff may have suffered were caused in whole or in part by the negligence, carelessness, and/or other wrongful conduct of other persons or entities over which J&J and Janssen had no control and for whose conduct J&J and Janssen are not responsible or liable.

20. Any imposition of liability, damages, penalties, or other relief against J&J or Janssen for the negligent, intentional, malicious, criminal, and/or other acts or omissions of parties or third parties not subject to J&J and/or Janssen's control or authority would violate J&J and Janssen's procedural and substantive due process rights under the Fourteenth Amendment to the United States Constitution and Article I, Section 19 of the Texas Constitution.

21. To the extent Plaintiff seeks relief for conduct not actionable at the time it occurred, Plaintiff's claims are barred because they violate J&J and Janssen's procedural and substantive due process rights under the Fourteenth Amendment to the United States Constitution and Article I, Section 19 of the Texas Constitution, and by J&J and Janssen's right to be free from retroactive or ex post facto laws as guaranteed by Article I, Section 10 of the United States Constitution and Article I, Section 16 of the Texas Constitution.

22. Plaintiff's claims are barred in whole or in part because the application of Texas law to conduct in other states or countries would violate the Dormant Commerce Clause of the United States Constitution.

23. Plaintiff's claims are preempted by federal and state law and any regulations or rules promulgated under such law, including, but not limited to, the federal Food, Drug, and Cosmetic Act ("FDCA"), associated U.S. Food and Drug Administration ("FDA") regulations,

the federal Controlled Substances Act, the Texas Food, Drug, and Cosmetic Act, and the Texas Controlled Substances Act. *See, e.g.*, 21 U.S.C. §§ 301 *et seq.*; 21 U.S.C. §§ 802 *et seq.*; 21 C.F.R. §§ 201.1 *et seq.*, 202.1 *et seq.*, 203.1 *et seq.*; Tex. Health & Safety Code §§ 431.001 *et seq.*; Tex. Health & Safety Code §§ 481 *et seq.*

24. Plaintiff's claims are preempted, in whole or in part, by federal law, to the extent that they are based on alleged misrepresentations made to the FDA, or otherwise assert that incorrect, incomplete, or inaccurate information was provided to the FDA. *See, e.g.*, *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013); *Buckman Co. v. Pls.' Legal Comm*., 531 U.S. 341 (2001); *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281 (6th Cir. 2015); *Geier v. Am. Honda Co.*, 529 U.S. 861 (2000).

25. Plaintiff's claims, if granted, would constitute an impermissible burden by this Court on federal laws, regulations, and policy relating to the development and marketing of prescription drugs in violation of the Supremacy Clause of the United States Constitution.

26. Plaintiff's claims are barred in whole or in part by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the FDCA and regulations promulgated under the FDCA.

27. Plaintiff's claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under the law with determining the content of warnings and labeling for products.

28. Plaintiff cannot state a claim with regard to warnings and labeling for products because the remedy sought by Plaintiff is subject to the exclusive regulation of the FDA.

29. Plaintiff's claims are barred in whole or in part because the warnings and instructions provided were adequate and complete. Janssen's products were neither defective

nor unreasonably dangerous when used according to the instructions for use. Indeed, the warnings and information that accompanied Janssen's products were approved by the FDA for a product approved under the FDCA and/or otherwise meet the presumption requirements in chapter 82 of the Texas Civil Practice and Remedies Code. *See* Tex. Civ. Prac. & Rem. Code §§ 82.007–.008

30. Plaintiff's claims are barred in whole or in part because J&J and Janssen's alleged misrepresentations and prescription opioid medications were not the legal or proximate cause of the purported nuisance or the alleged injuries or damages incurred by Plaintiff. Absent such causation, Plaintiff's claims cannot be sustained as a matter of law under the laws and common law of Texas and would also violate J&J and Janssen's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and Article I, Sections 3 and 19 of the Texas Constitution.

31. Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution, Article I, Section 8 of the Texas Constitution, and the *Noerr-Pennington* doctrine.

32. Plaintiff's request for exemplary/punitive damages is barred or limited in whole or in part, including by the following provisions: (a) chapter 41 of the Texas Civil Practice and Remedies Code, including the cap on exemplary damages set out in section 41.008 of that code; (b) the limits of the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution; (c) the excessive fines clause of the Eighth Amendment to the United States Constitution; (d) the Full Faith and Credit Clause of the United States Constitution; (e) the limits of the Double Jeopardy Clause of the Fifth Amendment to the United States Constitution and Article I, Section 14 of the Texas Constitution; and (f) other applicable provisions of the Texas

Constitution, as those limits have been applied by state and federal courts to restrict exemplary/punitive damages.

33. Plaintiff's common-law claims are barred, in whole or in part, by the doctrine of estoppel.

34. Plaintiff's claims are barred, in whole or in part, by principles of equity. Numerous facts would render the imposition of injunctive relief, civil penalties, or other remedies inequitable here, including but not limited to J&J's and Janssen's good faith reliance on and interpretation of clinical data and medical literature, the absence of any intentional unlawful conduct, the course of Plaintiff's investigation and pursuit of these claims, and J&J and Janssen's good faith reliance on guidance for product communications published by the FDA.

35. Plaintiff's claims are barred, in whole or in part, by the doctrine of waiver.

36. Plaintiff's claims are barred, in whole or in part, by the doctrines of release and/or res judicata.

37. Plaintiff's claims are barred in whole or in part by assumption of the risk.

38. Plaintiff's claims are barred in whole or in part by the sophisticated or knowledgeable user doctrine.

39. Plaintiff's claims are barred in whole or in part by informed consent.

40. In the unlikely event that J&J or Janssen are found liable to Plaintiff, J&J and Janssen are entitled to a credit or offset for any and all sums that Plaintiff has received, or may hereafter receive, by way of any and all settlements arising from Plaintiff's claims and causes of action.

41. Any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already or will in the future, with reasonable certainty, indemnify

Plaintiff in whole or in part for any past or future claimed economic loss from any collateral source.

42. Plaintiff's claims and damages are barred, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers by a state county.

43. Plaintiff's claims are barred and/or limited, in whole or in part, pursuant to applicable statutory and common law regarding limitations on awards, caps on recovery, and setoffs.

44. Plaintiff's claims are barred because its alleged injuries or damages, if any, were caused in whole or in part by Plaintiff's ratification of J&J's and/or Janssen's allegedly deceptive or misleading conduct.

45. Plaintiff's claims are barred in whole or in part by the doctrine of unclean hands.

46. Plaintiff's claims, injuries, and damages, if any, are barred, in whole or in part, by the alteration, modification, misuse, illicit use, or abuse of the prescribed medications by third parties, for which J&J and Janssen are not liable and over whom J&J and Janssen have no supervision or control and for whose actions and omissions J&J and Janssen have no responsibility.

47. As a matter of Texas law, Plaintiff is not entitled to a declaratory judgment, injunction, or attorney's fees for these or any other alleged claims.

48. J&J and Janssen may assert other defenses that become available or appear during the course of additional investigation or discovery in this case and hereby reserve the right to amend this answer to assert any such defense, consistent with the Texas Rules of Civil Procedure.

Prayer

49. For the reasons stated above, J&J and Janssen respectfully request that (1) Plaintiff take nothing in this lawsuit, (2) all of Plaintiff's claims be dismissed with prejudice, (3) J&J and Janssen recover any costs or attorney's fees to which J&J and Janssen are entitled or permitted by law, and (4) J&J and Janssen be granted such other and further relief, both at law and in equity, to which they are entitled.

Dated: May 3, 2019

Respectfully submitted,

By: */s/ Stephen E. McConnico*

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CERTIFICATE OF SERVICE

I certify that I caused a true and correct copy of the foregoing document to be electronically filed on May 3, 2019, which will transmit service electronically through the court's electronic filing manager to all counsel of record.

/s/ Stephen E. McConnico
Stephen E. McConnico

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

Certified Document Number: 85087453 Total Pages: 10

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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MDL PRETRIAL CAUSE NO. 2019-29777

COUNTY OF WALKER	§	**IN THE DISTRICT COURT**
	§	
Plaintiff,	§	
	§	
vs.	§	**152ND JUDICIAL DISTRICT**
	§	
PURDUE PHARMA L.P., et al.	§	
	§	
Defendants.	§	**HARRIS COUNTY, TEXAS**

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MASTER FILE NO. 2018-63587

	§	**IN THE DISTRICT COURT**
	§	
	§	
	§	
IN RE: TEXAS OPIOID LITIGATION	§	**152ND JUDICIAL DISTRICT**
	§	
	§	
	§	
	§	**HARRIS COUNTY, TEXAS**

PURDUE PHARMA L.P., PURDUE PHARMA INC., PURDUE PHARMACEUTICALS, L.P., AND THE PURDUE FREDERICK COMPANY, INC.'S ORIGINAL ANSWER TO PLAINTIFF'S ORIGINAL PETITION

Defendants Purdue Pharma L.P., Purdue Pharma Inc., Purdue Pharmaceuticals, L.P., and the Purdue Frederick Company, Inc. (together, "Purdue") file this Original Answer to Plaintiff's Original Petition and Jury Demand (the "Petition") and would respectfully show the following:

General Denial

1. Purdue generally denies the allegations in the Petition in accordance with Texas Rule of Civil Procedure 92. Purdue demands strict proof of all allegations made by Plaintiff, Walker County (the "County"), all as required by law, and further reserves the right to answer in greater particularity reasonably in advance of trial.

Affirmative and Other Defenses

2. Without assuming any burden of proof that it otherwise would not bear or admitting that it is in any way liable to the County, Purdue asserts that the County's claims against it are barred pursuant to the following defenses, each of which is raised in the alternative. Purdue expressly reserves the right to amend these defenses as permitted by the Texas Rules of Civil Procedure:

3. The County's claims against Purdue are barred, in whole or in part, by the applicable statute of limitations and/or repose.

4. The County's claims against Purdue are barred, in whole or in part, by its failure to mitigate damages.

5. The County's claims against Purdue are barred, in whole or in part, because the injury it alleges was the result of one or more criminal acts by unknown third parties, including without limitation, health care providers, prescribers, patients, and other third parties whom the County alleges engaged in the unauthorized or illicit prescription, dispensing, diversion, or use of prescription opioid products in Walker County, Texas. In accordance with Case Management Order No. 1, entered on December 26, 2018, Purdue will designate responsible third parties, including unknown criminal actors, under Section 33.004 of the Texas Civil Practice and Remedies Code no later than 60 days before the deadline for completing discovery in this case.

6. The County's claims against Purdue are barred, in whole or in part, by the learned intermediary doctrine.

7. The County's claims against Purdue are barred, in whole or in part, by the doctrines of waiver, equitable estoppel, quasi estoppel, and/or laches.

8. The County's claims against Purdue are barred, in whole or in part, by the doctrine of unclean hands.

9. The County's claims against Purdue are barred, in whole or in part, by res judicata and collateral estoppel.

10. The County's claims against Purdue are barred, in whole or in part, by the doctrine of release.

11. The County's claims against Purdue are barred, in whole or in part, because the First Amendment and/or Article I, Section 8 of the Texas Constitution protect Purdue's commercial and political speech.

12. The warnings and information that accompanied Purdue's products were approved by the FDA for a product approved under the FDCA and/or otherwise meet the presumption requirements in Section 82.007 of the Texas Civil Practice and Remedies Code. *See* Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a) (West 2011).

13. The County's claims against Purdue are barred and/or reduced by the assumption of risk, informed consent, contributory or comparative negligence, contributory or comparative fault, and proportionate responsibility.

14. The County's injuries and damages, if any, are barred, in whole or in part, by the actions, omissions, and/or conduct of third parties over whom Purdue had no control or authority and, thus, any recovery should be reduced or barred by such parties' proportionate fault. In accordance with Case Management Order No. 1, entered on December 26, 2018, Purdue will designate responsible third parties, including unknown criminal actors, under Section 33.004 of the Texas Civil Practice and Remedies Code no later than 60 days before the deadline for completing discovery in this case.

15. Any verdict or judgment that might be recovered by the County must be reduced by those amounts that have already or will in the future, with reasonable certainty, indemnify the County, in whole or in part, for any past or future claimed economic loss from any collateral source such as insurance, social security, workers' compensation, or employee benefit program.

16. Conduct at issue may solely be the result of an obligation imposed by law, and thus Purdue is entitled to complete indemnity, express or implied, by other parties.

17. The County's claims against Purdue are barred because they are preempted by federal law.

18. The County's claims against Purdue violate the Supremacy Clause of the United States Constitution.

19. The County's claims against Purdue are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the FDCA and regulations promulgated under the FDCA.

20. To the extent the County's claims against Purdue are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001).

21. The County cannot state a claim against Purdue with regard to warnings and labeling for products because the remedy sought by the County is subject to the exclusive regulation of the FDA.

22. The County's claims against Purdue regarding warnings and labeling are barred, in whole or in part, by the doctrine of primary jurisdiction, in that the FDA is charged under the law with determining the content of warnings and labeling for products.

23. The County's claims against Purdue are barred or limited by the economic loss rule.

24. Purdue's rights under the Due Process Clause of the U.S. Constitution are violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding.

25. The County's claim against Purdue for exemplary/punitive damages is subject to the following limitations: (a) Chapter 41 of the Texas Civil Practice and Remedies Code, including the cap on exemplary damages set out in Section 41.008 of that Code; and (b) the limits of the Due Process Clauses of the United States and Texas Constitutions, as those limits have been applied by state and federal courts to restrict exemplary damages.

26. The County's claims against Purdue are barred under the municipal cost recovery rule, which this Court should adopt.

27. The County's unjust enrichment claim against Purdue is barred because the County does not allege that Purdue wrongfully obtained a benefit from the County.

28. The County's claims against Purdue are barred because of unforeseeable alteration or misuse of the product or products at issue.

29. If the County has sustained any injuries or damages, such were the result of intervening or superseding events, factors, occurrences, or conditions, which were not reasonably foreseeable and in no way caused by Purdue and for which Purdue is not liable.

30. The County's claims against Purdue are barred because the marketing, manufacturing, and labeling of any alleged pharmaceutical products conformed with all applicable rules and the state of the art at the time.

31. The County's damages and claims against Purdue are barred or limited, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers by a state county.

32. The County's claims against Purdue are barred, reduced, and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and set-offs.

33. As applicable, Purdue would be entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasor(s) for the same injuries alleged in the Petition.

34. The County's claims against Purdue are not properly joined with the County's claims against the other defendants in this case because the claims do not arise out of the same alleged statements, actions, and omissions by all defendants in the case.

35. The County has failed to join one or more necessary and indispensable parties, including without limitation, health care providers, prescribers, patients, and other third parties whom the County alleges engaged in the unauthorized or illicit prescription, dispensing, diversion, or use of prescription opioid products in Walker County, Texas. In accordance with Case Management Order No. 1, entered on December 26, 2018, Purdue will designate responsible third parties, including unknown criminal actors, under Section 33.004 of the Texas Civil Practice and Remedies Code no later than 60 days before the deadline for completing discovery in this case.

36. The County's claims against Purdue are barred for lack of standing; the County has no parens patriae or other authority to bring the claims alleged, and the County fails to plead any basis for standing.

37. The County's claims against Purdue are barred because Purdue did not owe any legal duty to the County, or, if Purdue owed any such legal duty, Purdue did not breach that duty.

38. The County's fraud claims against Purdue are barred because they fail to allege any material misrepresentation made by Purdue.

39. As a matter of Texas law, the County is not entitled to a declaratory judgment, injunction, or attorney's fees for these alleged claims.

40. Purdue may assert other defenses that become available or appear during the course of additional investigation or discovery in this case. Purdue reserves the right to amend this answer to assert any such defense, consistent with the Texas Rules of Civil Procedure.

Jury Demand

41. Defendants Purdue Pharma L.P., Purdue Pharma Inc., Purdue Pharmaceuticals, L.P., and the Purdue Frederick Company, Inc. demand a jury trial and tender the appropriate fee with this answer.

Conclusion

Defendants Purdue Pharma L.P., Purdue Pharma Inc., Purdue Pharmaceuticals, L.P., and the Purdue Frederick Company, Inc. pray that the Court dismiss the claims against them with prejudice, enter a final take-nothing judgment in their favor, award them attorneys' fees and costs, and grant such other relief, legal or equitable, to which they are entitled.

Dated: May 3, 2019

Respectfully submitted,

/s/ Noelle M. Reed

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Counsel for Defendants Purdue Pharma L.P., Purdue Pharma Inc., Purdue Pharmaceuticals, L.P., and the Purdue Frederick Company, Inc.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the above was forwarded to all counsel of record via the Court's electronic filing system on May 3, 2019.

/s/ Noelle M. Reed
Noelle M. Reed

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

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HARRIS COUNTY, TEXAS

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MDL PRETRIAL CAUSE NO. 2019-29777

County of Walker *Plaintiff*,	§ §	IN THE DISTRICT COURT
v.	§ §	12th JUDICIAL DISTRICT
ABBOTT LABORATORIES, ET AL., *Defendants*.	§ §	WALKER COUNTY, TEXAS

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MASTER FILE NO. 2018-63587

	§	IN THE DISTRICT COURT
IN RE: TEXAS OPIOID LITIGATION	§ §	152nd JUDICIAL DISTRICT
	§	HARRIS COUNTY, TEXAS

ALLERGAN PLC'S SPECIAL APPEARANCE TO PRESENT
MOTION OBJECTING TO JURISDICTION

TO THE HONORABLE COURT:

Under Rule 120a of the Texas Rules of Civil Procedure, Allergan plc f/k/a Actavis plc makes this special appearance to object to the jurisdiction of the Court over its respective person and property. Allergan plc respectfully shows the Court the following:

1.
Purpose of Special Appearance

This special appearance is made to the entire proceeding.

2.
Special Appearance Motion Filed First

This special appearance motion is filed before any motion to transfer or any other plea, pleading, or motion filed by Allergan plc.

3.
Court Does Not Have Jurisdiction Over Allergan plc

As proved by the attached Declaration, this Court does not have personal jurisdiction—neither general nor specific—over Allergan plc, which is not amenable to process issued by the courts of Texas because:

A. Allergan plc has never consented nor agreed to the jurisdiction of Texas courts in this litigation;

B. Allergan plc is not a resident of Texas and is not required to maintain and does not maintain a registered agent for service in Texas;

C. Allergan plc does not now engage and has never engaged in business in Texas or committed any tort, in whole or in part, within the state;

D. Allergan plc does not maintain a place of business in Texas and has no employees, servants, or agents within the state;

E. Allergan plc has no substantial connection with Texas arising from any action or conduct of Allergan plc purposefully directed toward Texas;

F. Plaintiff's claims do not arise from and are not related to any activity conducted by Allergan plc in Texas; and

G. Allergan plc has no continuing and systematic contacts with Texas.

4.
Jurisdiction Deprives Allergan plc of Due Process

The assumption of jurisdiction by the Court over Allergan plc and its property would offend traditional notions of fair play and substantial justice, depriving Allergan plc of due process as guaranteed by the Constitution of the United States.

WHEREFORE, PREMISES CONSIDERED, Allergan plc respectfully requests that the Court set this motion for hearing on notice to Plaintiff, and that, after hearing, the Court grant this motion and dismiss the entire proceeding for lack of jurisdiction.

Dated: May 3, 2019

Respectfully submitted,

By: */s/ Wesley Hill*

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Attorneys specially appearing for Allergan plc f/k/a Actavis plc

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing instrument was served via the Court's electronic filing system on all counsel of record on May 3, 2019.

/s/ Wesley Hill
Wesley Hill

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

Certified Document Number: 85106183 Total Pages: 5

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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MASTER FILE NO. 2018-63587

IN RE: TEXAS OPIOID LITIGATION	§	IN THE DISTRICT COURT
	§	
MDL NO. 18-0358	§	152nd JUDICIAL DISTRICT
	§	
This Document Relates to All Cases	§	HARRIS COUNTY, TEXAS

DECLARATION OF JAMES D'ARECCA

STATE OF NEW JERSEY)
COUNTY OF MORRIS)

I, JAMES C. D'ARECCA, state:

1. I am the Senior Vice President and Chief Accounting Officer at Allergan plc.

2. Based on my position, experience, and review of relevant corporate records and information, I have personal knowledge of the facts set forth below, which I believe to be truthful and accurate, and to which I could and would competently testify if called as a witness.

3. Allergan plc f/k/a Actavis plc ("Allergan plc") is a corporation incorporated under the laws of the Republic of Ireland. Allergan plc's headquarters, and its only offices, are located in Ireland.

4. Although it was originally incorporated under the name Actavis plc in Ireland on May 16, 2013, Actavis plc changed its corporate name to Allergan plc in June 2015.

5. Allergan plc is a holding company that exists for the purpose of holding shares of other companies that manufacture and distribute prescription drugs rather than producing its own goods or services. Allergan plc does not finance or control the daily affairs of those companies. Allergan plc does not control the marketing or sales operations of those companies anywhere in the United States. Allergan plc also does not manufacture any goods or sell any products (including Kadian® or other opioids) or services either in the United States or anywhere else in the world.

6. Allergan plc operates separately and is independent of each of the companies in which it holds shares. For example, Allergan plc's corporate records, tax returns, and financial statements are kept separate from the companies in which it holds shares.

7. Allergan plc is not registered to do business anywhere in the United States. Allergan plc does not now conduct and has never conducted any business operations in the United States. Allergan plc does not lease or own any offices or facilities in the United States, and it has no employees in the United States (other than certain corporate officers and members of its Board of Directors who reside in the United States).

8. Allergan plc does not own Watson Laboratories, Inc. or Actavis Pharma, Inc.

9. Allergan plc does not now employ and has never employed any pharmaceutical sales representatives or marketing personnel. Allergan plc does not currently and has never manufactured, distributed, marketed, promoted, or sold any pharmaceutical products (including Kadian®) in the United States.

10. Allergan plc has no corporate filings on record with the Texas Secretary of State. It has not designated an agent for service of process in Texas, has no offices or employees in Texas, and does not send agents to solicit or conduct business in Texas.

11. Allergan plc does not now and has never participated in any U.S. federal or state government health care programs, including Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, the Federal Employee Health Benefit Program, and any other government health care program.

My name is James C. D'Arecca, my date of birth is [redacted], and my address is [redacted]. I declare under penalty of perjury that the foregoing is true and correct.

JAMES C. D'ARECCA

Executed in Morris County, State of New Jersey, on the 15thday of February, 2019.

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

Certified Document Number: 85106185 Total Pages: 3

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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MDL PRETRIAL CAUSE NO. 2019-29777

County of Walker *Plaintiff*,	§ §	IN THE DISTRICT COURT
v.	§ §	12th JUDICIAL DISTRICT
ABBOTT LABORATORIES, ET AL., *Defendants*.	§ §	WALKER COUNTY, TEXAS

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MASTER FILE NO. 2018-63587

	§	IN THE DISTRICT COURT
IN RE: TEXAS OPIOID LITIGATION	§ §	152nd JUDICIAL DISTRICT
	§	HARRIS COUNTY, TEXAS

ORDER SUSTAINING OBJECTION TO JURISDICTION

On _____, the Court heard *Allergan plc's Special Appearance to Present Motion Objecting to Jurisdiction*, whereby Defendant Allergan plc f/k/a Actavis plc moved the Court to dismiss this cause because Allergan plc is not amenable to process issued by the courts of this state. All parties to the proceedings, having been duly notified, appeared in person and/or through counsel. The Court, having considered the pleadings, evidence admitted for consideration, and arguments of counsel, is of the opinion and finds that the Court does not have jurisdiction of Allergan plc's person or property, and that the special appearance motion should be sustained. Accordingly,

IT IS ORDERED that *Allergan plc's Special Appearance to Present Motion Objecting to Jurisdiction* is sustained, and that this entire cause is dismissed for lack of jurisdiction.

Signed on _____, 2019

_____
HONORABLE ROBERT SCHAFFER
PRESIDING JUDGE
152nd District Court

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

Certified Document Number: 85106186 Total Pages: 2

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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MDL PRETRIAL CAUSE NO. 2019-29777

County of Walker *Plaintiff*,	§ §	IN THE DISTRICT COURT
v.	§ §	12th JUDICIAL DISTRICT
ABBOTT LABORATORIES, ET AL., *Defendants*.	§ §	WALKER COUNTY, TEXAS

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MASTER FILE NO. 2018-63587

	§	IN THE DISTRICT COURT
IN RE: TEXAS OPIOID LITIGATION	§ §	152nd JUDICIAL DISTRICT
	§	HARRIS COUNTY, TEXAS

ALLERGAN FINANCE, LLC'S
ORIGINAL ANSWER TO PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE COURT:

Defendant Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. files this Answer to Plaintiff's Original Petition.

General Denial

1. Allergan Finance, LLC generally denies the allegations in the Petition in accordance with Texas Rule of Civil Procedure 92. Allergan Finance, LLC demands strict proof of all allegations made by Plaintiff, all as required by law, and further reserves the right to answer in greater particularity reasonably in advance of trial.

Plea to the Jurisdiction

2. Plaintiff's claims are barred because the Court lacks subject matter jurisdiction, and Plaintiff fails to plead any basis for subject matter jurisdiction.

Affirmative and Other Defenses

Without assuming any burden of proof that it otherwise would not bear or admitting that it is in any way liable to Plaintiff, Allergan Finance, LLC asserts that Plaintiff's claims against it are barred pursuant to the following defenses, each of which is raised in the alternative. Allergan Finance, LLC expressly reserves the right to amend these defenses as permitted by the Texas Rules of Civil Procedure:

3. Plaintiff's claims are barred, in whole or in part, by the applicable statute of limitations.

4. Plaintiff's claims are barred, in whole or in part, by its failure to mitigate damages.

5. Plaintiff's claims are barred, in whole or in part, because the injury it alleges was the result of one or more criminal acts by third parties.

6. Plaintiff's claims are barred, in whole or in part, by the learned intermediary doctrine.

7. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver, estoppel, quasi estoppel, and/or laches.

8. Plaintiff's claims are barred, in whole or in part, because the First Amendment protects Allergan Finance, LLC's commercial and political speech.

9. The warnings and information that accompanied Allergan Finance, LLC's products were approved by the FDA for a product approved under the FDCA and/or otherwise meet the presumption requirements in Section 82.007 of the Texas Civil Practice and Remedies Code. *See* Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a) (West 2011).

10. The claims asserted in the Petition are barred and/or reduced by the assumption of risk, informed consent, contributory or comparative negligence, contributory or comparative fault, and proportionate responsibility.

11. Plaintiff's injuries and damages, if any, are barred in whole or in part by the actions, omissions, and/or conduct of third parties over whom Allergan Finance, LLC had no control or authority and, thus, any recovery should be reduced or barred by such parties' proportionate fault.

12. Any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already or will in the future, with reasonable certainty, indemnify Plaintiff in whole or in part for any past or future claimed economic loss from any collateral source such as insurance, social security, workers' compensation, or employee benefit program.

13. Allergan Finance, LLC's liability, if any, will not result from its conduct but is solely the result of an obligation imposed by law, and thus Allergan Finance, LLC is entitled to complete indemnity, express or implied, by other parties.

14. Plaintiff's claims are barred because they are preempted by federal law.

15. Plaintiff's claims violate the Supremacy Clause of the United States Constitution.

16. Plaintiff's claims are barred in whole or in part by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the FDCA and regulations promulgated under the FDCA.

17. To the extent Plaintiff's claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001).

18. Plaintiff cannot state a claim with regard to warnings and labeling for products because the remedy sought by Plaintiff is subject to the exclusive regulation of the FDA.

19. Plaintiff's claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under the law with determining the content of warnings and labeling for products.

20. Plaintiff's claims against Allergan Finance, LLC are barred or limited by the economic loss rule.

21. Allergan Finance, LLC's rights under the Due Process Clause of the U.S. Constitution are violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding.

22. Plaintiff's claim for exemplary/punitive damages is subject to the following limitations: (a) Chapter 41 of the Texas Civil Practice and Remedies Code, including the cap on exemplary damages set out in Section 41.008 of that Code; and (b) the limits of the Due Process Clause of the United States Constitution, as those limits have been applied by state and federal courts to restrict exemplary damages.

23. Plaintiff's claims against Allergan Finance, LLC are barred under the municipal cost recovery rule, which this Court should adopt.

24. If Plaintiff has sustained any injuries or damages, such were the result of intervening or superseding events, factors, occurrences or conditions, which were not reasonably foreseeable and in no way caused by Allergan Finance, LLC and for which Allergan Finance, LLC is not liable.

25. Plaintiff's claims and damages are barred or limited, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers by a state county.

26. The claims asserted in the Petition are barred, reduced, and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

27. Plaintiff's claims are barred because its alleged loss, damage, injury, harm, expense, diminution, or deprivation, if any, was caused in whole or in part by Plaintiff's ratification of Allergan Finance, LLC's allegedly deceptive or misleading conduct.

28. Should Allergan Finance, LLC be held liable to Plaintiff, which liability is specifically denied, Allergan Finance, LLC would be entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasor(s) for the same injuries alleged in the Petition.

29. Plaintiff's claims against Allergan Finance, LLC are not properly joined with Plaintiff's claims against the other defendants in this case because the claims do not arise out of the same alleged statements, actions, and omissions by all defendants in the case.

30. Plaintiff has failed to join one or more necessary and indispensable parties, including without limitation health care providers, prescribers, patients, and other third parties whom Plaintiff alleges engaged in the unauthorized or illicit prescription, dispensing, diversion, or use of prescription opioid products in Plaintiff's jurisdiction.

31. Plaintiff's claims are barred for lack of standing; plaintiff has no *parens patriae* or other authority to bring the claims alleged, and Plaintiff fails to plead any basis for standing.

32. Plaintiff fails to plead any duty owed to Plaintiff by Allergan Finance, LLC.

33. Plaintiff's fraud claims against Allergan Finance, LLC are barred because they fail to allege any material misrepresentation made by Allergan Finance, LLC.

34. As a matter of Texas law, Plaintiff is not entitled to a declaratory judgment, injunction, or attorney's fees for these alleged claims.

35. Allergan Finance, LLC may assert other defenses that become available or appear during the course of additional investigation or discovery in this case. Allergan Finance, LLC reserves the right to amend this answer to assert any such defense, consistent with the Texas Rules of Civil Procedure.

Jury Demand

36. Allergan Finance, LLC demands a jury trial and tenders the appropriate fee with this answer.

Conclusion

Allergan Finance, LLC prays that the Court dismiss the claims against it with prejudice, enter a final take-nothing judgment in its favor, award it attorneys' fees and costs, and grant such other relief, legal or equitable, to which it is entitled.

Dated: May 3, 2019

Respectfully submitted,

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Attorneys for Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing instrument was served via the Court's electronic filing system on all counsel of record on May 3, 2019.

/s/ Wesley Hill
Wesley Hill

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

Certified Document Number: 85106198 Total Pages: 8

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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MDL PRETRIAL CAUSE NO. 2019-29777

County of Walker *Plaintiff*,	§ §	IN THE DISTRICT COURT
v.	§ §	12th JUDICIAL DISTRICT
ABBOTT LABORATORIES, ET AL., *Defendants*.	§ §	WALKER COUNTY, TEXAS

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MASTER FILE NO. 2018-63587

	§	IN THE DISTRICT COURT
IN RE: TEXAS OPIOID LITIGATION	§	152nd JUDICIAL DISTRICT
	§	HARRIS COUNTY, TEXAS

ALLERGAN PLC'S
ORIGINAL ANSWER TO PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE COURT:

Subject to *Allergan plc's Special Appearance to Present Motion Objecting to Jurisdiction*, and without waiving said special appearance, Allergan plc f/k/a Actavis plc files this Original Answer and respectfully shows the Court the following:

1.
General Denial

Allergan plc generally denies the allegations in the Petition in accordance with Texas Rule of Civil Procedure 92. Allergan demands strict proof of all allegations made by Plaintiff, all as required by law, and further reserves the right to answer in greater particularity reasonably in advance of trial.

2.
Conclusion

Allergan plc respectfully requests that Plaintiff take nothing by this suit.

Dated: May 3, 2019

Respectfully submitted,

By: */s/ Wesley Hill*
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Tex. Bar No. 24065750
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Attorneys specially appearing for Allergan plc f/k/a Actavis plc

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing instrument was served via the Court's electronic filing system on all counsel of record on May 3, 2019.

/s/ Wesley Hill
Wesley Hill

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

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Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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Filed: 5/6/2019 9:10 AM

MDL PRETRIAL CAUSE NO. 2019-29777

COUNTY OF WALKER, *Plaintiff,*	§ §	IN THE DISTRICT COURT
V.	§ §	12TH JUDICIAL DISTRICT
PURDUE PHARMA, L.P., ET AL., *Defendants.*	§ §	WALKER COUNTY, TEXAS

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MASTER FILE NO. 2018-63587

IN RE: TEXAS OPIOID LITIGATION	§ § § §	IN THE DISTRICT COURT 152ND JUDICIAL DISTRICT HARRIS COUNTY, TEXAS

DEFENDANT CEPHALON, INC.'S ORIGINAL ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S ORIGINAL PETITION

Defendant Cephalon, Inc. (hereinafter "Defendant" or "Cephalon")[1] files its Original Answer and Affirmative Defenses to the Original Petition (the "Petition") of the County of Walker ("Plaintiff" or the "County"), and shows as follows:

I. GENERAL DENIAL

1. Pursuant to Rule 92 of the Texas Rules of Civil Procedure, Cephalon denies each and every allegation contained in the County's Original Petition and respectfully request that the

[1]Cephalon's parent corporation, Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), is an Israeli corporation that is not subject to personal jurisdiction in the United States. Teva Ltd. has not been served, does not join in this filing, and contests personal jurisdiction.

Court require the County to prove its allegations by a preponderance of the believable evidence as the Constitution and laws of the State of Texas require.

II. AFFIRMATIVE DEFENSES

2. Without assuming any burden of proof that it otherwise would not bear or admitting that it is in any way liable to the County, Cephalon asserts that the County's claims against it are barred pursuant to the following defenses, each of which is raised in the alternative. Cephalon expressly reserves the right to amend these defenses as permitted by the Texas Rules of Civil Procedure.

3. The County's claims are barred, in whole or in part, because it lacks standing to bring the claims it asserts. The County has no constitutional, statutory, *parens patriae*, or other authority to bring the claims alleged, and the County fails to plead any basis for standing.

4. The County's claims are barred, in whole or in part, by the applicable statute of limitations and/or repose.

5. The County's claims are barred, in whole or in part, by its failure to mitigate damages.

6. The County's claims are barred, in whole or in part, because Cephalon has no legal duty to protect the County from the criminal acts of third parties, and the injury it alleges was the result of one or more criminal acts by third parties.

7. The County's damages, if any, were proximately caused, in whole or in part, by independent, intervening, or superseding causes, including acts and omissions of others over whom Cephalon had no control or right of control.

8. The County's claims are barred, in whole or in part, by the learned intermediary doctrine.

9. The County's claims are barred, in whole or in part, by the doctrines of waiver, estoppel, quasi estoppel, unclean hands, and/or laches.

10. The County's claims are barred, in whole or in part, by the applicable provisions of the United States Constitution and the Texas Constitution, including but not limited to the First Amendment to the United States Constitution, the Supremacy Clause of the United States Constitution, and/or Article I, Section 8 of the Texas Constitution.

11. The County's claims are barred, in whole or in part, by the assumption of risk.

12. The County's claims are barred, in whole or in part, by the doctrine of informed consent.

13. The County's claims are barred, in whole or in part, by the doctrines of contributory or comparative negligence, contributory or comparative fault, and/or proportionate responsibility.

14. The County's claims are barred, in whole or in part, because they are preempted by federal law.

15. The County's claims are barred, in whole or in part, by the doctrine of primary jurisdiction.

16. The County's claims are barred, in whole or in part, by Texas Civil Practice and Remedies Code § 82.007.

17. The County's claims are barred, in whole or in part, by the economic loss rule.

18. The County's claims are barred, in whole or in part, by the municipal cost recovery rule.

19. The County's claims are barred, at least in part, by a prior settlement and release.

20. The County's claims against Cephalon are not properly joined, under Texas Rule of Civil Procedure 40, with the County's claims against the other defendants in this case because

the claims do not arise out of the same alleged statements, actions, and omissions by all defendants in the case.

21. The County has failed to join one or more necessary and indispensable parties, including, without limitation, health care providers, prescribers, patients, and other third parties whom the County alleges engaged in the unauthorized or illicit prescription, dispensing, diversion, or use of prescription opioid products in Walker County, Texas.

22. Cephalon is entitled to complete indemnity, express or implied, by other parties.

23. The County's claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the FDCA and regulations promulgated under the FDCA.

24. To the extent the County's claims against Cephalon are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to *Buckman Co. v. The County's Legal Committee*, 531 U.S. 341 (2001).

25. The County cannot state a claim against Cephalon with regard to warnings and labeling for products because the remedy sought by the County is subject to the exclusive regulation of the FDA.

26. The County's claim against Cephalon for exemplary/punitive damages is subject to the following limitations: (a) Chapter 41 of the Texas Civil Practice and Remedies Code, including the cap on exemplary damages set out in Section 41.008 of that Code; and (b) the limits of the Due Process Clauses of the United States and Texas Constitutions, as those limits have been applied by state and federal courts to restrict exemplary damages.

27. The County's injuries or damages, if any, were the result of intervening or superseding events, factors, occurrences or conditions, that were not reasonably foreseeable and in no way caused by Cephalon, and for which Cephalon is not liable.

28. The County's claims against Cephalon are barred because the manufacturing and labeling of its opioid products conformed with all applicable rules and regulations, and the state of the art at the time.

29. The County's damages and claims against Cephalon are barred or limited, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers by a county of a state.

30. The County's claims against Cephalon are barred, reduced, and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

31. As applicable, Cephalon would be entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasor(s) for the same injuries alleged in the Petition.

32. Any verdict or judgment that might be recovered by the County must be reduced by those amounts that have already or will in the future, with reasonable certainty, be used to indemnify the County in whole or in part for any past or future claimed economic loss from any collateral source such as insurance, social security, workers' compensation, or employee benefit program(s).

33. The County's claims against Cephalon are barred because of alteration or misuse of the product or products at issue.

34. The County's claims against Cephalon are barred because Cephalon did not owe any legal duty to the County, or, if Cephalon owed any such legal duty, Cephalon did not breach that duty.

35. The County's claims against Cephalon are barred because the County suffered no cognizable injuries or damages as a result of Cephalon's conduct or actions.

36. The Petition and each claim contained therein fails to state a claim upon which relief can be granted, fails to state facts sufficient to constitute a cause of action, and fails to plead a legally cognizable injury.

37. The claims asserted in the Petition against Cepahlon are barred, in whole or in part, by the FDA-approved TIRF REMS Program, including, but not limited to, the requirements imposed on prescribers of TIRF medicines and patients.

38. The County's claims are barred, in whole or in part, to the extent they are based on alleged harms resulting from known risks or dangers associated with opioid products that are unavoidable even within the scope of prescribed and intended use, but that are reasonable in comparison to the benefits conferred.

39. The alleged injury asserted by the County is too remote from the alleged conduct of Cephalon to be a basis for liability as a matter of law and due process.

40. The County may not recover from Cephalon because the methods, standards, or techniques of designing, manufacturing, labeling and distributing of the prescription medications at issue complied with and were in conformity with the generally recognized state of the art at the time the product was designed, manufactured, labeled, and distributed.

41. The County's claims are barred, in whole or in part, by the voluntary payment doctrine.

42. The County's claims or damages are invalid and/or are barred, in whole or in part, because the users of the medications at issue used them after acknowledging and/or learning of their alleged risks.

43. The County's injuries and damages, if any, were due to preexisting conditions, idiosyncratic reactions, or other responses to the medications on the part of the medication users, for which Cephalon cannot be held responsible. The opioid medications at issue were manufactured, distributed, and labeled, in accordance with the provisions of federal law, including the U.S. Food Drug and Cosmetics Act, and the regulations promulgated pursuant thereto. Moreover, the activities alleged conformed with all state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time(s) alleged.

44. The County's claims may be barred, in whole or in part, because neither users nor prescribers relied to their detriment upon any statement by Cephalon in determining to use the medications at issue, particularly given the TIRF REMS Access Program, required by the FDA, that mandates prescriber enrollment in order to prescribe TIRF medicines.

45. The County's claims are barred because the conduct of Cephalon conformed with the FDCA, the requirements of the FDA, the Controlled Substances Act, and the requirements of the DEA. Moreover, the activities of Cephalon alleged in the Petition conformed with all state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time(s) alleged in the Petition.

46. The County cannot establish that it incurred any costs for any opioid prescription promoted or sold by Cephalon and that was medically inappropriate or should not have been written, or that Cephalon's allegedly improper conduct caused any health care provider to write any unnecessary, ineffective or harmful opioid prescriptions.

47. Any statements in branded or unbranded materials that the County seeks to attribute to Cephalon comporting with FDA-approved uses are not misleading as a matter of law or otherwise actionable.

48. The County cannot establish any actionable misrepresentation or omission made by or attributable to Cephalon.

49. The County's claims are barred because they violate procedural and substantive due process rights under the U.S. Constitution and the Texas Constitution.

50. To the extent the County attempts to seek equitable relief, the County is not entitled to such relief because the County has an adequate remedy at law and cannot otherwise satisfy the elements for equitable relief.

51. The County's claims are barred or limited by the separation of powers doctrine.

52. The County seeks duplicate or double recovery on the same injury or damage, contrary to Texas law.

53. The County's damages, if any, were not proximately caused by any act or omission attributable to Cephalon.

54. As a matter of law, the County is not entitled to equitable relief, including but not limited to a declaratory judgment or injunction, or attorney's fees for these alleged claims.

55. The County's claim of public nuisance is barred or limited because Cephalon did not engage in any conduct in Walker County that contributed to any public nuisance.

56. To the extent the County seeks punitive, exemplary, or aggravated damages, any such damages are barred because the products at issue, and their labeling, were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

57. To the extent the County seeks to impose liability on Cephalon for broad, general statements regarding the value or quality of Cephalon's products that were made to and reasonably understood by providers as opinion, such statements cannot constitute false representations as a matter of law.

58. To the extent any agents, employees, or contractors of Cephalon caused any of the damages alleged by the County, such agents, employees, or contractors were acting outside the scope of the agency employment, or contract with Cephalon, and any recovery against Cephalon must be reduced by the proportionate fault of such agents, employees, or contractors.

59. To the extent the County's claims are based on the alleged conduct of other Defendants, and the County seeks to impose liability on Cephalon only by virtue of Cephalon's ownership of another Defendant's shares, membership within another Defendant's unincorporated entity, or similar affiliation, the County cannot prove any allegations sufficient to support a claim to pierce the corporate veil or to otherwise hold Cephalon liable merely by virtue of their corporate affiliation with any other Defendant.

60. The representations or statements alleged to have been made were true and accurate at the time made and/or otherwise were made in good faith, with a reasonable belief as to their validity and accuracy and with a reasonable belief that all conduct was lawful.

61. The County's claims are barred by the sophisticated user doctrine.

62. The County cannot identify any concerted action by Cephalon to participate in any conspiracy.

63. Any defendant's liability must be limited in accordance with the percentage of fault allocated to it by the ultimate trier of fact and/or law. Each defendant may only be severally liable

for any injuries or expenses. The County's alleged damages are not indivisible but comprise separate and discrete costs.

64. The County's claims are barred, in whole or in part, by the Commerce Clause of the United States Constitution.

III. PRAYER

65. Cephalon seeks a judgment that includes the following relief:

a. An order that the County take nothing from Cephalon;

b. An order dismissing the County's claims against Cephalon with prejudice;

c. Court costs; and

d. All other relief to which Cephalon is entitled.

Dated: May 6, 2019

Respectfully submitted,

/s/ Nancy Patterson

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Counsel for Defendant Cephalon, Inc.

CERTIFICATE OF SERVICE

In accordance with the Texas Rules of Civil Procedure, I certify that a true and correct copy of the foregoing instrument has been served on all counsel of record via electronic service on May 6, 2019.

/s/ Nancy Patterson
Nancy Patterson

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

Certified Document Number: 85107462 Total Pages: 12

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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MDL PRETRIAL CAUSE NO. 2019-29777

COUNTY OF WALKER, *Plaintiff,*	§ §	IN THE DISTRICT COURT
V.	§ §	12TH JUDICIAL DISTRICT
PURDUE PHARMA, L.P., ET AL., *Defendants.*	§ §	WALKER COUNTY, TEXAS

****

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MASTER FILE NO. 2018-63587

IN RE: TEXAS OPIOID LITIGATION	§ § § §	IN THE DISTRICT COURT 152ND JUDICIAL DISTRICT HARRIS COUNTY, TEXAS

DEFENDANTS ACTAVIS LLC, ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA INC., AND ACTAVIS ELIZABETH LLC'S ORIGINAL ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S ORIGINAL PETITION

Defendants Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., and Actavis Elizabeth LLC (collectively, the "Acquired Generic Actavis Entities")[1] file their Original Answer and Affirmative Defenses to the Original Petition (the "Petition") of the County of Walker ("Plaintiff" or the "County"), and show as follows:

[1] The Acquired Generic Actavis Entities' parent corporation, Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), is an Israeli corporation that is not subject to personal jurisdiction in the United States. Teva Ltd. has not been served, does not join in this filing, and contests personal jurisdiction.

I. GENERAL DENIAL

1. Pursuant to Rule 92 of the Texas Rules of Civil Procedure, the Acquired Generic Actavis Entities deny each and every allegation contained in the County's Original Petition and respectfully request that the Court require the County to prove its allegations by a preponderance of the believable evidence as the Constitution and laws of the State of Texas require.

II. AFFIRMATIVE DEFENSES

2. Without assuming any burden of proof that they otherwise would not bear or admitting that they are in any way liable to the County, the Acquired Generic Actavis Entities assert that the County's claims against them are barred pursuant to the following defenses, each of which is raised in the alternative. The Acquired Generic Actavis Entities expressly reserve the right to amend these defenses as permitted by the Texas Rules of Civil Procedure.

3. The County's claims are barred because the Acquired Generic Actavis Entities sold generic medicines and did not promote them, and the County has not asserted and cannot assert any allegations of wrongdoing by the Acquired Generic Actavis Entities.

4. The County's claims are barred, in whole or in part, because it lacks standing to bring the claims it asserts. The County has no constitutional, statutory, *parens patriae*, or other authority to bring the claims alleged, and the County fails to plead any basis for standing.

5. The County's claims are barred, in whole or in part, by the applicable statute of limitations and/or repose.

6. The County's claims are barred, in whole or in part, by its failure to mitigate damages.

7. The County's claims are barred, in whole or in part, because the Acquired Generic Actavis Entities have no legal duty to protect the County from the criminal acts of third parties, and the injury it alleges was the result of one or more criminal acts by third parties.

8. The County's damages, if any, were proximately caused, in whole or in part, by independent, intervening, or superseding causes, including acts and omissions of others over whom the Acquired Generic Actavis Entities had no control or right of control.

9. The County's claims are barred, in whole or in part, by the learned intermediary doctrine.

10. The County's claims are barred, in whole or in part, by the doctrines of waiver, estoppel, quasi estoppel, unclean hands, and/or laches.

11. The County's claims are barred, in whole or in part, by the applicable provisions of the United States Constitution and the Texas Constitution, including but not limited to the First Amendment to the United States Constitution, the Supremacy Clause of the United States Constitution, and/or Article I, Section 8 of the Texas Constitution.

12. The County's claims are barred, in whole or in part, by the assumption of risk.

13. The County's claims are barred, in whole or in part, by the doctrine of informed consent.

14. The County's claims are barred, in whole or in part, by the doctrines of contributory or comparative negligence, contributory or comparative fault, and/or proportionate responsibility.

15. The County's claims are barred, in whole or in part, because they are preempted by federal law.

16. The County's claims are barred, in whole or in part, by the doctrine of primary jurisdiction.

17. The County's claims are barred, in whole or in part, by Texas Civil Practice and Remedies Code § 82.007.

18. The County's claims are barred, in whole or in part, by the economic loss rule.

19. The County's claims are barred, in whole or in part, by the municipal cost recovery rule.

20. The County's claims against the Acquired Generic Actavis Entities are not properly joined, under Texas Rule of Civil Procedure 40, with the County's claims against the other defendants in this case because the claims do not arise out of the same alleged statements, actions, and omissions by all defendants in the case.

21. The County has failed to join one or more necessary and indispensable parties, including, without limitation, health care providers, prescribers, patients, and other third parties whom the County alleges engaged in the unauthorized or illicit prescription, dispensing, diversion, or use of prescription opioid products in Walker County, Texas.

22. The Acquired Generic Actavis Entities are entitled to complete indemnity, express or implied, by other parties.

23. The County's claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the FDCA and regulations promulgated under the FDCA.

24. To the extent the County's claims against the Acquired Generic Actavis Entities are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to *Buckman Co. v. The County's Legal Committee*, 531 U.S. 341 (2001).

25. The County cannot state a claim against the Acquired Generic Actavis Entities with regard to warnings and labeling for products because the remedy sought by the County is subject to the exclusive regulation of the FDA.

26. The County's claim against the Acquired Generic Actavis Entities for exemplary/punitive damages is subject to the following limitations: (a) Chapter 41 of the Texas Civil Practice and Remedies Code, including the cap on exemplary damages set out in Section 41.008 of that Code; and (b) the limits of the Due Process Clauses of the United States and Texas Constitutions, as those limits have been applied by state and federal courts to restrict exemplary damages.

27. The County's injuries or damages, if any, were the result of intervening or superseding events, factors, occurrences or conditions, that were not reasonably foreseeable and in no way caused by the Acquired Generic Actavis Entities, and for which the Acquired Generic Actavis Entities are not liable.

28. The County's claims against the Acquired Generic Actavis Entities are barred because they did not engage in any marketing of any opioid products, and the manufacturing and labeling of their opioid products conformed with all applicable rules and regulations, and the state of the art at the time.

29. The County's damages and claims against the Acquired Generic Actavis Entities are barred or limited, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers by a county of a state.

30. The County's claims against the Acquired Generic Actavis Entities are barred, reduced, and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

31. As applicable, the Acquired Generic Actavis Entities would be entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasor(s) for the same injuries alleged in the Petition.

32. Any verdict or judgment that might be recovered by the County must be reduced by those amounts that have already or will in the future, with reasonable certainty, be used to indemnify the County in whole or in part for any past or future claimed economic loss from any collateral source such as insurance, social security, workers' compensation, or employee benefit program(s).

33. The County's claims against the Acquired Generic Actavis Entities are barred because of alteration or misuse of the product or products at issue.

34. The County's claims against the Acquired Generic Actavis Entities are barred because the Acquired Generic Actavis Entities did not owe any legal duty to the County, or, if the Acquired Generic Actavis Entities owed any such legal duty, the Acquired Generic Actavis Entities did not breach that duty.

35. The County's claims against the Acquired Generic Actavis Entities are barred because the County suffered no cognizable injuries or damages as a result of the Acquired Generic Actavis Entities' conduct or actions.

36. The Petition and each claim contained therein fails to state a claim upon which relief can be granted, fails to state facts sufficient to constitute a cause of action, and fails to plead a legally cognizable injury.

37. Any claims pertaining to generic medicines are preempted, as set forth in the United States Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mutual Pharmaceuticals Co. v. Bartlett*, 570 U.S. 472 (2013).

38. The claims asserted in the Petition against the Acquired Generic Actavis Entities are barred, in whole or in part, by the FDA-approved TIRF REMS Program, including, but not limited to, the requirements imposed on prescribers of TIRF medicines and patients.

39. The County's claims are barred, in whole or in part, to the extent they are based on alleged harms resulting from known risks or dangers associated with opioid products that are unavoidable even within the scope of prescribed and intended use, but that are reasonable in comparison to the benefits conferred.

40. The alleged injury asserted by the County is too remote from the alleged conduct of the Acquired Generic Actavis Entities to be a basis for liability as a matter of law and due process.

41. The County may not recover from the Acquired Generic Actavis Entities because the methods, standards, or techniques of designing, manufacturing, labeling and distributing of the prescription medications at issue complied with and were in conformity with the generally recognized state of the art at the time the product was designed, manufactured, labeled, and distributed.

42. The County's claims are barred, in whole or in part, by the voluntary payment doctrine.

43. The County's claims or damages are invalid and/or are barred, in whole or in part, because the users of the medications at issue used them after acknowledging and/or learning of their alleged risks.

44. The County's injuries and damages, if any, were due to preexisting conditions, idiosyncratic reactions, or other responses to the medications on the part of the medication users, for which the Acquired Generic Actavis Entities cannot be held responsible. The opioid

medications at issue were manufactured, distributed, and labeled, in accordance with the provisions of federal law, including the U.S. Food Drug and Cosmetics Act, and the regulations promulgated pursuant thereto. Moreover, the activities alleged conformed with all state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time(s) alleged.

45. The County's claims may be barred, in whole or in part, because neither users nor prescribers relied to their detriment upon any statement by the Acquired Generic Actavis Entities in determining to use the medications at issue, particularly given the TIRF REMS Access Program, required by the FDA, that mandates prescriber enrollment in order to prescribe TIRF medicines.

46. The County's claims are barred because the conduct of the Acquired Generic Actavis Entities conformed with the FDCA, the requirements of the FDA, the Controlled Substances Act, and the requirements of the DEA. Moreover, the activities of the Acquired Generic Actavis Entities alleged in the Petition conformed with all state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time(s) alleged in the Petition.

47. The County cannot establish that it incurred any costs for any opioid prescription promoted or sold by the Acquired Generic Actavis Entities and that was medically inappropriate or should not have been written, or that the Acquired Generic Actavis Entities' allegedly improper conduct caused any health care provider to write any unnecessary, ineffective or harmful opioid prescriptions.

48. Any statements in branded or unbranded materials that the County seeks to attribute to the Acquired Generic Actavis Entities comporting with FDA-approved uses are not misleading as a matter of law or otherwise actionable.

49. The County cannot establish any actionable misrepresentation or omission made by or attributable to the Acquired Generic Actavis Entities.

50. The County's claims are barred because they violate procedural and substantive due process rights under the U.S. Constitution and the Texas Constitution.

51. To the extent the County attempts to seek equitable relief, the County is not entitled to such relief because the County has an adequate remedy at law and cannot otherwise satisfy the elements for equitable relief.

52. The County's claims are barred or limited by the separation of powers doctrine.

53. The County seeks duplicate or double recovery on the same injury or damage, contrary to Texas law.

54. The County's damages, if any, were not proximately caused by any act or omission attributable to the Acquired Generic Actavis Entities.

55. As a matter of law, the County is not entitled to equitable relief, including but not limited to a declaratory judgment or injunction, or attorney's fees for these alleged claims.

56. The County's claim of public nuisance is barred or limited because the Acquired Generic Actavis Entities did not engage in any conduct in Walker County that contributed to any public nuisance.

57. To the extent the County seeks punitive, exemplary, or aggravated damages, any such damages are barred because the products at issue, and their labeling, were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

58. To the extent the County seeks to impose liability on the Acquired Generic Actavis Entities for broad, general statements regarding the value or quality of the Acquired Generic

Actavis Entities' products that were made to and reasonably understood by providers as opinion, such statements cannot constitute false representations as a matter of law.

59. To the extent any agents, employees, or contractors of the Acquired Generic Actavis Entities caused any of the damages alleged by the County, such agents, employees, or contractors were acting outside the scope of the agency employment, or contract with the Acquired Generic Actavis Entities, and any recovery against the Acquired Generic Actavis Entities must be reduced by the proportionate fault of such agents, employees, or contractors.

60. To the extent the County's claims are based on the alleged conduct of other Defendants, and the County seeks to impose liability on the Acquired Generic Actavis Entities only by virtue of the Acquired Generic Actavis Entities' ownership of another Defendant's shares, membership within another Defendant's unincorporated entity, or similar affiliation, the County cannot prove any allegations sufficient to support a claim to pierce the corporate veil or to otherwise hold the Acquired Generic Actavis Entities liable merely by virtue of their corporate affiliation with any other Defendant.

61. The representations or statements alleged to have been made were true and accurate at the time made and/or otherwise were made in good faith, with a reasonable belief as to their validity and accuracy and with a reasonable belief that all conduct was lawful.

62. The County's claims are barred by the sophisticated user doctrine.

63. The County cannot identify any concerted action by the Acquired Generic Actavis Entities to participate in any conspiracy.

64. Any defendant's liability must be limited in accordance with the percentage of fault allocated to it by the ultimate trier of fact and/or law. Each defendant may only be severally liable

for any injuries or expenses. The County's alleged damages are not indivisible but comprise separate and discrete costs.

65. The County's claims are barred, in whole or in part, by the Commerce Clause of the United States Constitution.

III. PRAYER

66. The Acquired Generic Actavis Entities seek a judgment that includes the following relief:

a. An order that the County take nothing from any of the Acquired Generic Actavis Entities;

b. An order dismissing the County's claims against each and every of the Acquired Generic Actavis Entities with prejudice;

c. Court costs; and

d. All other relief to which the Acquired Generic Actavis Entities are individually or collectively entitled.

Dated: May 6, 2019

Respectfully submitted,

/s/ Nancy Patterson

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CERTIFICATE OF SERVICE

In accordance with the Texas Rules of Civil Procedure, I certify that a true and correct copy of the foregoing instrument has been served on all counsel of record via electronic service on May 6, 2019.

/s/ Nancy Patterson
Nancy Patterson

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

Certified Document Number: 85107506 Total Pages: 13

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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TRIAL CAUSE NO. 1929076

COUNTY OF WALKER	§	**IN THE DISTRICT COURT**
	§	
Plaintiff,	§	
	§	
v.	§	**12TH JUDICIAL DISTRICT**
	§	
ABBOTT LABORATORIES, et al.	§	
	§	
Defendants.	§	**WALKER COUNTY, TEXAS**

MDL PRETRIAL CAUSE NO. 2019-29777

COUNTY OF WALKER	§	**IN THE DISTRICT COURT**
	§	
Plaintiff,	§	
	§	
v.	§	**152ND JUDICIAL DISTRICT**
	§	
ABBOTT LABORATORIES, et al.	§	
	§	
Defendants.	§	**HARRIS COUNTY, TEXAS**

MCKESSON CORPORATION AND MCKESSON MEDICAL-SURGICAL, INC.'S ORIGINAL ANSWER TO PLAINTIFF'S ORIGINAL PETITION

Defendants McKesson Corporation and McKesson Medical-Surgical, Inc. ("Defendants" or "McKesson") file their Original Answer and Defenses to Plaintiff's Original Petition and in support show the following:

I.
General Denial

Pursuant to Rule 92 of the Texas Rules of Civil Procedure, Defendants assert a general denial, deny each and every allegation made by Plaintiff County of Walker, and demand strict proof thereof.

II.
Affirmative & Other Defenses

Without accepting the burden of proof on any issue on which McKesson does not have the burden as a matter of law, McKesson sets forth the following affirmative and other defenses.

1. Plaintiff lacks standing to assert some or all of its claims.

2. Plaintiff has no authority or right to bring such claims on behalf of itself or the citizens of Walker County.

3. Plaintiff has no capacity, authority, or right to assert some or all of its claims, including claims brought indirectly on behalf of its citizens or claims brought as *parens patriae*.

4. McKesson asserts that it is not liable in the capacity in which it has been sued.

5. Plaintiff's claims are barred because Plaintiff is not the real party in interest.

6. Defendants further plead, if such be necessary, and pleading in the alternative, that Plaintiff's claims are barred by the doctrine of *in pari delicto*.

7. Plaintiff's claims are subject to all the defenses that could be asserted if Plaintiff's claims were properly made by individuals on whose behalf or for whose alleged damages Plaintiff seeks to recover.

8. The derivative injury rule and the remoteness doctrines bar Plaintiff from recovering payments that Plaintiff allegedly made on behalf of residents to reimburse any expenses for health care, pharmaceutical care, and other public services.

9. The alleged injuries asserted by Plaintiff are too remote from the alleged conduct of Defendants to provide a basis for liability as a matter of law and due process.

10. Plaintiff's damages and claims against Defendants are barred or limited, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers by a state county.

11. Plaintiff's petition fails in whole or in part to state a claim upon which relief can be granted, fails to state sufficient facts sufficient to constitute a cause of action, and fails to plead cognizable injury.

12. Plaintiff's claims are preempted, in whole or in part, by federal law, including without limitation the federal Controlled Substances Act and the Food, Drug, and Cosmetic Act.

13. Plaintiff's claims are barred, in whole or in part, by conflict preemption, as set forth in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

14. Plaintiff's claims are preempted insofar as they conflict with Congress's purposes and objectives in enacting relevant federal legislation and authorizing regulations, including the Hatch-Waxman amendments to the FDCA and implementing regulations. *See Geier v. Am. Honda Co*, 529 U.S. 861 (2000).

15. Plaintiff's claims are barred in whole or in part by the Dormant Commerce Clause of the United States Constitution.

16. Plaintiff's claims are barred, in whole or in part, by the deference that common law accords discretionary actions by the FDA under the FDCA and discretionary actions by the DEA under the Controlled Substances Act.

17. Plaintiff's claims are barred, in whole or in part, for failure to exhaust administrative remedies.

18. Plaintiff's claims are barred in whole or in part to the extent that they violate the Due Process Clause of the United States and Texas Constitutions.

19. Plaintiff's claims are barred, in whole or in part, to the extent that they violate the Ex Post Facto clauses of the United States and Texas Constitutions.

20. Plaintiff cannot obtain relief on its claims based on actions undertaken by Defendants of which Defendants provided notice of all reasonable facts.

21. Defendants did not owe or breach any duty to Plaintiff.

22. Defendants appropriately, completely, and fully discharged any and all obligations and legal duties arising out of the matters alleged in the Petition.

23. Plaintiff's claims are not ripe, and/or have been mooted.

24. Defendants have no legal duty to protect Plaintiff from the intentional criminal acts of third persons. The criminal conduct of a third party is a superseding cause that extinguishes liability. Plaintiff's alleged damages were caused by the intentional and criminal activities of unidentified persons over which Defendants had no right of control.

25. Plaintiff is barred by the free public services/municipal cost recovery doctrine from recovering costs incurred in providing public services.

26. Plaintiff's claims are barred, in whole or in part, by the economic loss rule.

27. Plaintiff's claims are barred by all applicable statutes of limitation and repose.

28. Plaintiff's claims are barred in whole or in part by Plaintiffs' knowledge of alleged falsity and/or acquiescence.

29. Plaintiff's claims are barred in whole or in part by the doctrine of avoidable consequences.

30. Plaintiff's claims are barred by consent.

31. Plaintiffs' claims are barred by ratification and/or condonation.

32. The alleged injuries were not legally foreseeable.

33. The claims raised by Plaintiff are barred by the doctrines of laches, waiver, ratification, estoppel, unclean hands, quasi-estoppel, and/or equitable estoppel.

34. Plaintiff's claims are barred in whole or in part by the doctrines of acquiescence, settlement and or release.

35. If Defendants are found liable to Plaintiff in any amount, Defendants are entitled to a credit or set-off for any and all sums Plaintiff has received in the way of any and all settlements and for all sums of money received or available from or on behalf of any tortfeasor(s) for the same injuries alleged in the Petition. Defendants have a right under Chapters 32 and 33 of the Texas Civil Practice & Remedies Code to a proportionate reduction of any damages found against them, based on the product, negligence, or other conduct of any settling tortfeasor and/or responsible third-party. Under Texas Civil Practices and Remedies Code, Chapter 33, Plaintiff is proportionately responsible for any damage it alleges to have suffered with respect to the claims asserted against McKesson. Therefore, Plaintiff's claims are barred in whole or in part by their contributory fault.

36. McKesson pleads for, and is entitled to, a comparative fault submission under Chapter 33 of the Texas Civil Practice and Remedies Code which will compare the fault of all Parties and responsible third parties.

37. Any damages that Plaintiff may recover against Defendants must be reduced to the extent that Plaintiff is seeking damages for alleged injuries or expenses related to the same user(s) of the subject prescription medications, or damages recovered or recoverable by other actual or potential plaintiffs. Any damages that Plaintiffs may recover against Defendants must be reduced to the extent they unjustly enrich Plaintiff.

38. Plaintiff's claims are barred, in whole or in part, by *res judicata* and collateral estoppel.

39. Plaintiff's claims are barred or limited by the terms and effect of any applicable Consent Judgment, including by operation of the doctrines of *res judicata* and collateral estoppel, failure to fulfill conditions precedent, failure to provide requisite notice, payment, accord and satisfaction, and compromise and settlement.

40. Any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already indemnified or with reasonable certainty will indemnify Plaintiff in whole or in part for any past or future claimed economic loss from any collateral source or any other applicable law.

41. Plaintiff's damages, if any, were proximately caused, in whole or in part, by independent, intervening, or superseding causes, events, factors, occurrences, or conditions, which were not reasonably foreseeable and not caused by Defendants and for which Defendants are not liable.

42. Any and all damages alleged by Plaintiff were caused by misuse of the products involved, failure to use the products properly, and/or alteration of, or criminal misuse or abuse of the product by third parties over whom Defendants had no control and for whom Defendants are not responsible.

43. Plaintiff suffered no injuries or damages as a result of any action by Defendants.

44. No conduct of Defendants was misleading, unfair, or deceptive.

45. Plaintiff's claims are barred, in whole or in part, by its failures to mitigate its alleged damages.

46. Any and all damages claimed by Plaintiff, whether actual, compensatory, punitive, attorneys' fees, or otherwise are subject to all applicable statutory and common law exclusions, caps, and limitations.

47. Plaintiff's claims for punitive or exemplary damages are barred because Plaintiff cannot prove by clear and convincing evidence that McKesson was grossly negligent and McKesson has neither acted nor failed to act in a manner that entitled Plaintiff to recover punitive or exemplary damages.

48. Plaintiff's alleged damages are speculative, uncertain, and hypothetical.

49. Plaintiff's claims are barred and/or reduced by the assumption of risk, informed consent, contributory or comparative negligence, contributory or comparative fault, and proportionate responsibility. McKesson asserts its right of contribution under Texas law with respect to any settling person, responsible party or tortfeasor, and McKesson invokes all protections contained within Chapter 41 of the Texas Civil Practice and Remedies Code.

50. Plaintiff's claims or damages are barred because users of the medications at issue used them after they knew, or should have known, of their alleged risks.

51. Defendants deny all types of causation including without limitation cause in fact, proximate cause and producing cause, with respect to the claims asserted against Defendants.

52. Plaintiff's claims and alleged damages are barred under the learned intermediary doctrine because adequate warnings were given to learned intermediaries.

53. Plaintiff's damages, if any, were the direct result of circumstances over which Defendants had and continue to have no control.

54. All of the limitations and requirements contained in Chapter 41 of the Texas Civil Practice and Remedies Code, and all federal and Texas constitutional limitations upon the assessment of punitive or exemplary damages, including those stated in the decisions of *BMW of North America v. Gore*, 116 S. Ct. 1589 (1996) and *State Farm Mutual Insurance Co. v. Campbell*, 538 U.S. 408 (2003), preclude an award of punitive or exemplary damages.

55. Plaintiff's claims fail to the extent they are based on a theory of market share liability, which is not a recognized means for recovering damages under Texas law.

56. Plaintiff's claims based on alleged violations of industry customs fail because purported industry customs do not create legal duties on Defendants.

57. Defendants are not liable to Plaintiff because Defendants are a non-manufacturing seller under Texas Civil Practice & Remedies Code § 82.003.

58. Pursuant to Texas Civil Practice & Remedies Code § 82.007, Defendants are not liable with respect to any allegations involving failure to provide adequate warning or information because all of the warning or information that accompanied the allegedly distributed products were approved by the United States Food & Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 *et seq*.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended, or the warnings and information provided were those stated in monographs developed by the United States Food & Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.

59. Plaintiff's claims are barred or limited to the extent they have been abrogated by the Texas Products Liability Act, Texas Civil Practice & Remedies Code Chapter 82.

60. The conduct of Defendants conformed with the FDCA and the requirements of the FDA, the Controlled Substances Act, and DEA regulations, and the activities of Defendants alleged in the Petition conformed with all state and federal statutes, regulations, and industry standards based on the state of knowledge at the relevant time(s) alleged in the Petition.

61. Defendants are not liable for any injury allegedly caused to Plaintiff by the products in question because all formulations, labeling, and design of the products complied with

mandatory safety standards or regulations adopted and promulgated by the federal government, or an agency of the federal government, applicable to the products at the time of manufacture and that governed the product risk that allegedly caused the purported harm.

62. Plaintiff may not recover against Defendants because the methods, standards, or techniques of designing, manufacturing, labeling and distributing of the prescription medications at issue complied with and were in conformity with the generally recognized state of the art at the time the product was designed, manufactured, labeled, and distributed.

63. Plaintiff would be unjustly enriched if allowed to recover on any of their claims.

64. Plaintiff's claims are barred, in whole or in part, by application of the doctrine of release.

65. Plaintiff's claims are barred, in whole or in part, because the First Amendment and/or Article I, Section 8 of the Texas Constitution protect Defendants' commercial and political speech.

66. To the extent Plaintiff's claims depend solely on violations of federal law, including any claims of "fraud on the DEA" with respect to Defendants' compliance with statutes or regulations administered and/or enforced by the DEA, such claims are barred and should be dismissed. *See Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001).

67. To the extent that Plaintiff relies on letters or other informal guidance from the DEA to establish Defendants' regulatory duties, such informal guidance cannot enlarge Defendants' regulatory duties in the absence of compliance by DEA with the requirements of the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*

68. Plaintiff cannot state a claim against Defendants with regard to warnings and labeling for products because the remedy sought by the County is subject to the exclusive regulation of the FDA.

69. To the extent Plaintiff seeks punitive, exemplary, or aggravated damages, any such damages are barred because the product at issue, and its labeling were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

70. Plaintiff's claims are barred, in whole or in part, because federal agencies have exclusive or primary jurisdiction over the matters asserted in Plaintiff's petition.

71. Plaintiff has failed to join one or more necessary and indispensable parties, including without limitation healthcare providers, prescribers, patients, and other third parties whom the County alleges engaged in the unauthorized or illicit prescription, dispensing, diversion, or use of prescription opioid products in Walker County.

72. Plaintiff's damages, if any, were the direct result of pre-existing medical conditions, and/or occurred by operation of nature or as a result of circumstances over which Defendants had and continue to have no control.

73. Plaintiff's injuries and damages, if any, were due to pre-existing conditions or idiosyncratic reaction to the medications on the part of the medication users, for which Defendants cannot be held responsible.

74. Plaintiff's claims are barred, in whole or in part, because neither users nor their prescribers relied to their detriment upon any statement by Defendants in determining to use medications at issue.

75. Plaintiff's claims are barred, in whole or in part, by the Restatement (Second) of Torts § 402A, Comments j and k, and Restatement (Third) of Torts: Products Liability § 6.

76. Defendants are not liable for statements or omissions in the Manufacturer Defendants' branded or unbranded materials.

77. Plaintiff's claims are barred in whole or in part because no statement or conduct of McKesson was misleading, unfair, or deceptive.

78. To the extent Plaintiff seeks relief for Defendants' conduct occurring before enactment of applicable statutes or regulations, the claims fail because the statutes and regulations do not apply retroactively.

79. McKesson's rights under the Due Process Clause of the U.S. Constitution and applicable state Constitution or statute are violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding, including by Plaintiffs' use of a contingency fee contract with private counsel.

80. Plaintiff's claims are barred or limited by the political question and separation of powers doctrines and because this case implicates issues of statewide importance that are reserved for state regulation.

81. Plaintiff's claims or damages are barred because users of medications at issue used them illegally and not after properly being prescribed the medication by a licensed health care provider.

82. The claims asserted against McKesson and other Defendants do not arise out of the same transactions or occurrences as required for joinder of parties.

83. Defendants' liability, if any, will not result from its conduct, but is solely the result of an obligation imposed by law, and thus McKesson is entitled to indemnity, express or implied, by other parties.

84. Plaintiff failed to plead that they reimbursed any prescriptions for any opioid distributed by Defendants that harmed patients and should not have been written or that Defendants' allegedly improper conduct caused a health care provider to write an ineffective or harmful opioid prescription.

85. To the extent Plaintiff attempts to seek equitable relief, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

86. Plaintiff has failed to comply with the requirement that they identify each patient in whose claim(s) they have a subrogation interest.

87. Plaintiff's public nuisance claim is barred or limited to the extent that they lack the statutory authority to bring a nuisance claim under Texas law or their own applicable county or municipal codes or regulations.

88. Plaintiff's claim of public nuisance is barred or limited because (i) no action of McKesson involved interference with real property, (ii) illegal conduct perpetrated by third parties involving use of an otherwise legal product does not involve a public right against the distributor sufficient to state a claim for public nuisance, (iii) the alleged public nuisance would have impermissible extraterritorial reach, and (iv) the alleged conduct of Defendants is too remote from the alleged injury as a matter of law and due process.

89. Plaintiff's claims for punitive or exemplary damages or other civil penalties are barred or reduced by applicable law or statute, or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, and applicable provisions of the Constitution of this State. Any law, statute, or other authority purporting to permit the recovery of punitive damages or civil penalties in this case is

unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages or civil penalties and/or the amount, if any; (2) is void for vagueness in that it fails to provide adequate notice as to what conduct will result in punitive damages or civil penalties; (3) unconstitutionally may permit recovery of punitive damages or civil penalties based on harms to third parties, out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) unconstitutionally may permit recovery of punitive damages or civil penalties in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to McKesson; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any award of punitive damages or civil penalties; (7) lacks constitutionally sufficient standards for appellate review of any award of punitive damages or civil penalties; (8) would unconstitutionally impose a penalty, criminal in nature, without according to Defendants the same procedural protections that are accorded to criminal defendants under the constitutions of the United States, this State, and any other state whose laws may apply; and (9) otherwise fails to satisfy Supreme Court precedent, including without limitation, *Pacific Mut. Life Ins. Co. v. Halisp*, 499 U.S. 1 (1991); *TXO Prod. Corp. v. Alliance Res. Inc.*, 509 U.S. 443 (1993); *BMW of N. Am. v. Gore*, 517 U.S. 559 (1996); *State Farm Ins. Co. v. Campbell*, 533 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007).

90. Defendants deny all liability under the Texas Controlled Substances Act (the "TCSA").

91. Defendants did not knowingly divert controlled substances for the unlawful use or benefit of another person.

92. Defendants did not knowingly distribute, deliver, administer, or dispense controlled substances in violation of the Texas Controlled Substances Act or with no valid medical purpose.

93. Defendants did not fail to report signs of any alleged abuse, diversion, and inappropriate prescribing. Defendants reported all information related to opioid orders as required under both state and federal law, as applicable.

94. There is no private of action in the Texas Controlled Substances Act or its legislative rules against Defendants. Plaintiff lacks the authority to file suit to collect penalties or fines based on alleged violations of the Texas Controlled Substances Act.

95. Plaintiff's claims are barred by the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution and Article 1, § 19 of the Texas Constitution because substantive due process forbids the retroactive imposition of changing and unclear legal interpretations of the Texas Controlled Substances Act.

96. Plaintiff's claims are barred, in whole or in part, because Defendants are not a "practitioner" under Texas Health & Safety Code § 481.071.

97. Defendants may rely upon any other applicable affirmative defense(s) set forth in any Answer of any other defendant in this action and reserve the right to amend this answer to assert any further defenses.

III.
Prayer

Defendants respectfully request that Plaintiff take nothing by reason of this suit, that this lawsuit be discharged, and that Defendants be awarded costs of court and any other and further relief, both general and special, at law and in equity, to which it may be justly entitled.

Respectfully submitted,

SMYSER KAPLAN & VESELKA, LLP

By: */s/ Craig Smyser*
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Counsel for McKesson Corporation

CERTIFICATE OF SERVICE

I hereby certify that on May 6, 2019, a true and correct copy of the above and foregoing was forwarded to all counsel of record via electronic service.

/s/ *Craig Smyser*
Craig Smyser

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

Certified Document Number: 85110328 Total Pages: 17

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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Filed: 5/6/2019 10:11 AM

TRIAL CAUSE NO. 1929076

COUNTY OF WALKER	§	**IN THE DISTRICT COURT**
	§	
Plaintiff,	§	
	§	
vs.	§	**12TH JUDICIAL DISTRICT**
	§	
ABBOTT LABORATORIES, et al.	§	
	§	
Defendants.	§	**WALKER COUNTY, TEXAS**

****

MDL PRETRIAL CAUSE NO. 2019-29777
(MDL MASTER CAUSE NO. 2018-63587)

	§	**IN THE DISTRICT COURT**
	§	
	§	
	§	
IN RE TEXAS OPIOID LITIGATION	§	**152ND JUDICIAL DISTRICT**
	§	
	§	
	§	
	§	**HARRIS COUNTY, TEXAS**

****

DEFENDANT FRESENIUS KABI USA'S
ORIGINAL ANSWER TO PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

Defendant Fresenius Kabi USA files this Original Answer to the Petition filed by Plaintiff County of Walker. In support thereof, Defendant respectfully pleads as follows:

I.
GENERAL DENIAL

1. Pursuant to Texas Rule of Civil Procedure 92, Fresenius Kabi USA generally denies each and every allegation in Plaintiff's Petition and demands strict proof of all allegations made therein as required by law.

II.
PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Defendant Fresenius Kabi USA prays that the Court grant judgment on behalf of Defendant; that Plaintiff takes nothing by the above-captioned action; that Defendant recover its costs of court; and that Defendant be awarded such other and further relief, at law or in equity, to which it may be justly entitled.

Respectfully submitted,

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ATTORNEYS FOR DEFENDANT
FRESENIUS KABI USA

CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the above and foregoing has been served upon counsel for all parties of record via the Court's notification system, on this 6th day of May, 2019, as follows:

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/s/ Kate Semmler Cornelius
Kate Semmler Cornelius

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

Certified Document Number: 85110985 Total Pages: 4

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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COUNTY OF WALKER,	*	**IN THE DISTRICT COURT**
Plaintiff,	*	**152ND DISCTRICT COURT OF**
v.	*	**HARRIS COUNTY, TEXAS**
ABBOTT LABORATORIES, et al.,	*	**MDL PRETRIAL CAUSE NO.**
Defendants.	*	**2019-29777**

* * * * * * * * * * * * *

NOTICE OF FILING OF RULE 11 LETTER AGREEMENT.

Please take notice that, pursuant to Texas Rule of Civil Procedure 11, Abbott Laboratories and Abbott Laboratories Inc. (collectively, "Abbott") file the attached Rule 11 Letter Agreement agreed to and approved by counsel for Abbott and counsel for Plaintiff Walker County.

Dated: May 6, 2019

Respectfully Submitted,

/s/ *John McCauley*
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Attorneys for Defendants Abbott Laboratories and Abbott Laboratories Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served through the Court's electronic filing system on May 6, 2019 to all counsel of record.

/s/ *Alper Ertas*
Alper Ertas

I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this May 7, 2019

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Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

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Cause No. 1929076

COUNTY OF WALKER,	§	IN THE DISTRICT COURT OF
Plaintiff,	§	
v.	§	12th JUDICIAL DISTRICT
ABBOTT LABORATORIES, et al.,	§	
Defendants.	§	WALKER COUNTY, TEXAS

DEFENDANT NAVITUS MANAGEMENT, LLC's ORIGINAL ANSWER

TO THE HONORABLE DONALD KRAEMER:

Defendant, NAVITUS MANAGEMENT, LLC ("Navitus") files its Original Answer to the Original Petition filed by Plaintiff, the County of Walker ("Walker County"), and states:

General Denial

1.

Defendant Navitus generally denies every allegation contained in Walker County's Original Petition and demands strict proof thereof.

Plaintiff Sued the Wrong Defendant

2.

Navitus denies it is a proper party to this suit. The Navitus Management, LLC that Plaintiff Walker County is attempting to sue has its corporate headquarters in Madison, Wisconsin and is a pharmacy benefits manager. Defendant Navitus has a name similar to the intended defendant but is engaged in the oil and gas business in Texas.

Defendant Navitus is not in the pharmacy business and does not sell or distribute opioid drugs. Thus, Plaintiff Walker County sued the wrong defendant.

Prayer

WHEREFORE, PREMISES CONSIDERED, Defendant Navitus prays (1) Plaintiff Walker County take nothing by reason of its suit; (2) Defendant Navitus recover its costs and attorney's fees; and (3) for such other and further relief to which it may be entitled.

Respectfully submitted,

/s/ David B. McCall

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Fax: (512) 482-0924

Counsel for Defendant,
Navitus Management, LLC

Certificate of Service

I certify that on May 7, 2019 a copy of the forgoing *Defendant Navitus Management, LLC's Original Answer* was served on the following counsel of record:

Via eService
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Counsel for Plaintiff Walker County

Via eService
Via Email: mpark@parkdurham.com
Mr. Mance Michael "Mike" Park
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Counsel for Plaintiff Walker County

/s/ David B. McCall
David B. McCall

CAUSE NO. 1929076

COUNTY OF WALKER,	§	**IN THE DISTRICT COURT**
	§	
Plaintiff,	§	
	§	
vs.	§	**12TH JUDICIAL DISTRICT**
	§	
ABBOTT LABORATORIES, ET AL,	§	
	§	
Defendants.	§	**WALKER COUNTY, TEXAS**
	§	

****

MDL MASTER CAUSE NO. 2018-63587

	§	**IN THE DISTRICT COURT**
	§	
	§	
	§	
IN RE TEXAS OPIOID LITIGATION	§	**152ND JUDICIAL DISTRICT**
	§	
	§	
	§	
	§	**HARRIS COUNTY, TEXAS**

****

DEFENDANT J M SMITH CORPORATION'S ORIGINAL ANSWER

Defendant J M Smith Corporation ("Smith Drug" or "Defendant"), improperly sued as "JM Smith Corporation d/b/a QS/1Data Systems of JM Smith Corporation," files this Original Answer to Plaintiff County of Walker's ("Walker County" or "Plaintiff") Original Petition as follows:

I.
GENERAL DENIAL

Pursuant to Texas Rule of Civil Procedure 92, Smith Drug generally denies each and every allegation contained in Plaintiff's Original Petition and any subsequent petition or amendment thereto, and demands strict proof thereof at the time of trial.

II.
SPECIAL DENIAL

Pursuant to Rule 54 of the Texas Rules of Civil Procedure, Smith Drug specifically denies that Plaintiff properly pleaded that all conditions precedent to Plaintiff's claims have been performed or have occurred, and denies that such conditions precedent have been met in their entirety.

III.
SPECIAL EXCEPTIONS

Smith Drug asserts the following exceptions under Texas Rule of Civil Procedure 91:

1. **No Texas cause of action for public nuisance:** Public nuisance does not exist as a cause of action under Texas law.

2. **No duty to support a negligence or gross-negligence claim:** Plaintiff did not assert a duty it was owed by Smith Drug—and indeed no duty exists from Smith Drug to Plaintiff.

3. **No alleged breach of duty to support a negligence or gross-negligence claim:** Plaintiff did not assert that Smith Drug breached a duty owed to Plaintiff.

4. **No proximate cause to support a negligence or gross-negligence claim:** Plaintiff did not plead facts to support foreseeability or cause in fact in its claims against Smith Drug.

5. **Smith Drug is not a "practitioner" under Texas Health & Safety Code § 481.071:** Smith Drug is not a "practitioner" as defined by Texas Health & Safety Code § 481.002(39)(A), and thus, is not liable under Texas Health & Safety Code § 481.071.

6. **Failure to plead basis for recovery of attorney's fees:** Plaintiff has stated no basis for the recovery of attorney's fees.

7. **Failure to plead basis for injunctive relief.** Plaintiff has not alleged the necessary elements to support injunctive relief.

IV.
AFFIRMATIVE DEFENSES

Smith Drug, still urging and relying on the matters alleged above, further alleges by way of affirmative defenses (and/or as any other appropriate pleading) the following, and to the extent necessary, each of the defenses set forth below are pled in the alternative.

1. **Lack of Standing:** Plaintiff does not have standing to assert claims against Smith Drug.

2. **Failure to State a Claim:** Plaintiff fails to state facts sufficient to constitute a claim upon which an award of actual damages, compensatory damages, restitutionary damages, punitive damages, or other relief may be granted.

3. **Lack of Capacity:** Plaintiff lacks capacity to bring its claims, including claims indirectly maintained on behalf of its citizens and claims brought as *parens patriae*. In the alternative, Plaintiff's claims are barred because Plaintiff is not the real party in interest.

4. **No Justiciable Issue:** Plaintiff has failed to assert claims over which the Court has the power to exercise its authority.

5. **Failure to add all necessary and indispensable parties:** Plaintiff failed to join one or more necessary and indispensable parties, including, but not limited to, the DEA, healthcare providers, prescribers, patients, and other third parties whom Plaintiff alleges engaged in the prescription, dispensing, diversion or use of the subject prescription medications.

6. **Free Public Services Doctrine:** Plaintiff is precluded from recovering its alleged damages through civil litigation because, under the "free public services" doctrine, a government entity may not recover its expenditures made in discharging public duties.

7. **Derivative Injury Rule:** Plaintiff cannot recover payment that Plaintiff allegedly made on behalf of residents to reimburse the costs of health care, pharmaceutical treatment, incarceration, and other public services because recovery for such expenses is barred by the derivative injury rule. Any alleged harm to Plaintiff is wholly derivative of harm suffered by a third party—the resident taxpayers—and thus the remoteness doctrine bars recovery.

8. **Due Process Protections:** Smith Drug's right under the Due Process Clause of the United States Constitution and applicable state Constitution or statute are violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding, including by Plaintiff's use of a contingency-fee contract with private counsel.

9. **Federal Preemption:** Plaintiff's claims are in whole or in part preempted by Federal law:

a. In the alternative, Plaintiff's claims are barred, in whole or in part, by conflict preemption as set forth in the United States Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) and *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

b. In the alternative, Plaintiff's claims are preempted insofar as they conflict with Congress's purposes and objectives in enacting relevant federal legislation and authorizing regulations.

c. In the alternative, to the extent Plaintiff claims that Smith Drug misled or defrauded DEA or any federal agency by failing to report suspicious pharmacy

orders or other information, such claims are preempted by federal law. *See Buckman v. The Countys' Legal Comm'n*, 531 U.S. 341 (2001).

10. **No Duty Owed to Plaintiff:** Smith Drug did not owe or breach any duty to Plaintiff.

11. **Third-Party Criminal Acts:** Smith Drug has no legal duty to protect Plaintiff from the intentional criminal acts of third persons. The criminal conduct of third parties is a superseding cause that extinguishes any liability.

12. **No Causal Link:** Smith Drug denies the alleged causal link between its alleged conduct and Plaintiff's harm or damages. In particular, Smith Drug denies cause in fact, proximate cause or producing cause, and foreseeability. The occurrences and injuries alleged by Plaintiff were caused by the conduct, criminal diversion, and misuse or abuse of legal products by third parties over whom Smith Drug had no control or for whom Smith Drug was not responsible.

13. **Statute of Limitations:** Plaintiff's claims are barred by the applicable statutes of limitations.

14. **Statute of Repose:** Plaintiff's claims are barred by the applicable statutes of repose.

15. **Intervening Acts:** Smith Drug cannot be held liable for any subsequent superseding and intervening acts of other parties or persons or Acts of God that harmed Plaintiff.

16. **New & Independent Cause:** Plaintiff's alleged damages resulted from new and independent, unforeseeable, superseding and/or intervening causes unrelated to any conduct of J M Smith.

17. **Unforeseeable:** Any injuries or damages alleged in the Petition may have been caused by unforeseeable and uncontrollable circumstances and/or other forces over which Smith Drug had no control and for which Smith Drug is not responsible, including pre-existing medical conditions.

18. **Failure to Mitigate:** The damages, if any, recoverable by Plaintiff must be reduced by any amount of damages legally caused by the Plaintiff's failure to mitigate such damages in whole or in part.

19. **Contributory Negligence:** Plaintiff's claims are barred as a result of Plaintiff's own negligence, which contributed in whole or in part to its alleged damages. Alternatively, Plaintiff's recovery, if any, should be reduced by the percentage of Plaintiff's contributory negligence.

20. **Waiver and Estoppel:** Plaintiff's claims are barred by the doctrines of waiver, estoppel, laches, and/or assumption of risk.

21. **Misuse of Product:** Any and all damages alleged by Plaintiff were caused by misuse of the products involved, failure to use the products properly, and/or alteration of or criminal misuse or abuse of the product by third parties over whom Smith Drug had no control and for whom Smith Drug is not responsible.

22. **Nonmanufacturing Seller:** Smith Drug is not liable for any of Plaintiff's alleged "injuries" because Smith Drug is a non-manufacturing seller under Texas Civil Practice & Remedies Code § 82.003.

23. **Product Warnings and Information Approved by United States Food & Drug Administration:** Pursuant to Texas Civil Practice & Remedies Code § 82.007, Smith Drug is not liable with respect to any allegations involving failure to provide adequate warnings

or information because all warnings or information that accompanied the allegedly distributed products were approved by the United States Food & Drug Administration for a product approved under the Federal Food, Drug & Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended, or the warnings and information provided were those stated in monographs developed by the United States Food & Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.

24. **Compliance with Government Standards:** Under Texas Civil Practice & Remedies Code § 82.008, Smith Drug is not liable for any injury allegedly caused to Plaintiff by the prescription opioid products because all formulations, labeling, and design of the products complied with mandatory safety standards or regulations adopted and promulgated by the federal government, or an agency of the federal government, that were applicable to the products at the time of manufacture and that governed the product risk that allegedly caused the purported harm.

25. **Speculative Alleged Damages:** In the alternative, Plaintiff's alleged damages are speculative, uncertain, and hypothetical.

26. **Punitive Damages Unconstitutional and Statutory Cap:** Smith Drug denies Plaintiff's punitive-damages claims and asserts that those claims violate federal and state laws and statutes. Any award of punitive damages would violate Smith Drug's due-process rights guaranteed by the United States Constitution and the due-process provisions of the Texas Constitution, and would be improper under the common law and public policies of the State of Texas. Any award of punitive damages would also violate the Texas Civil Practice and Remedies Code, Chapter 41. Also, any award of exemplary or punitive damages, in the absence of appropriate standards, would be unreasonable, arbitrary, capricious, and confiscatory, and

have no relation to any fact, and, therefore, afford Smith Drug no adequate means of defense. In addition, the appropriate amount of punitive damages, if any, must be established by clear and convincing evidence. Further, any claim for punitive damages is subject to the statutory cap under the Texas Civil Practices and Remedies Code.

27. **Comparative Responsibility:** This action is subject to the proportionate responsibility provisions of Chapter 33 of the Tex. Civ. Prac. & Rem. Code, including (without limitation) the requirement of § 33.003 thereof that the trier of fact determine the relative responsibility of each claimant, defendant, settling person, and responsible third-party who may be joined in the suit. Smith Drug denies that it was a joint tortfeasor. Smith Drug raises contributory negligence, comparative negligence, and comparative causation as affirmative defenses. Based on Texas law, Smith Drug is entitled to a reduction of any judgment that might be rendered against it. The reduction should be based on the degree of causation, negligence, or responsibility attributed to Plaintiff, other defendants, and any responsible third parties, including settling parties. Further, Smith Drug asserts its right to a dollar-for-dollar settlement credit pursuant to the Texas Civil Practices and Remedies Code.

28. **Responsible Third Parties – Unknown Criminals Under Texas Civil Practice & Remedies Code § 33.004(j):** Plaintiff's alleged "damages" were caused by numerous unknown persons who abused, misused, wrongfully obtained, illegally trafficked or diverted, and/or sold prescription opioids in violation of criminal law. The purported public expenditures of which Plaintiff complains stem from, among other things, investigations, arrests, incarcerations, medical treatments, mental-health treatments, and other public-service responses to the unknown criminals' intentional and criminal activities. As required by § 33.004(k), Smith

Drug will refer to these unknown criminals as the "Does" until their identities are known because this case and discovery are in their infancy.

29. **Sophisticated User and Learned Intermediary:** Smith Drug cannot be held liable for any alleged damages caused to Plaintiff because the products at issue were prescribed by sophisticated medical providers and dispensed by sophisticated pharmacists who were learned intermediaries with knowledge equal to or greater than Smith Drug. *See Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 169–70 (Tex. 2012) (applying the learned-intermediary doctrine to all of plaintiff's claims and explaining that, where a prescribing physician is aware of a drug's risks, "any inadequacy of the product's warning, as a matter of law, is not the producing cause of the patient's injuries.").

30. **Assumption of the Risk and Informed Consent:** Any recovery against Smith Drug is barred or limited under the principles of assumption of the risk and informed consent.

31. **No Claim for Public Nuisance:** Smith Drug's claim of public nuisance is barred or limited because no action of Smith Drug involved interference with real property; illegal conduct perpetrated by third parties involving the use of an otherwise legal product does not involve a public right against the distributor sufficient to state a claim for public nuisance; the alleged public nuisance would have impermissible extraterritorial reach; and the alleged conduct of Smith Drug is too remote from the alleged injury as a matter of law and due process.

32. **No Cause of Action Under Texas Controlled Substances Act:** In the alternative, there is no cause of action in the Texas Controlled Substances Act or its legislative rules against Smith Drug. Also, Plaintiff lacks the authority to file suit to collect penalties or fines based on alleged violations of the Texas Controlled Substances Act.

PRAYER

WHEREFORE, PREMISES CONSIDERED, Smith Drug prays that Plaintiff's Original Petition be dismissed with prejudice, the relief requested by the Plaintiff be denied, and that all costs be taxed against Plaintiff. Additionally, Smith Drug prays for such other and further relief, either at law or in equity, special or general, to which it may be deemed justly entitled.

Respectfully submitted,

FOX ROTHSCHILD LLP

By: _____

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CERTIFICATE OF SERVICE

I certify that on this the 3rd day of May, 2019, a true and correct copy of the foregoing document was served on all counsel of record in accordance with the Texas Rules of Civil Procedure.

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K. Patrick Babb